EXHIBIT 3

AO 88A (Rev. 12/20) Subpoena to Testify at a Deposition in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Delaware

Apple Inc.	)	
Plaintiff	)	
v.	)	Civil Action No. 22-cv-1378-MN-JLH
Masimo Corporation and Sound United, LLC	)	
	)	
Defendant	)	

SUBPOENA TO TESTIFY AT A DEPOSITION IN A CIVIL ACTION

To: Sotera Health Company, 9100 South Hills Blvd, Suite 300, Broadview Heights, OH 44147
c/o Corporation Service Company, 251 Little Falls Drive, Wilmington, DE 19808

(Name of person to whom this subpoena is directed)

☑ Testimony: YOU ARE COMMANDED to appear at the time, date, and place set forth below to testify at a deposition to be taken in this civil action. If you are an organization, you must promptly confer in good faith with the party serving this subpoena about the following matters, or those set forth in an attachment, and you must designate one or more officers, directors, or managing agents, or designate other persons who consent to testify on your behalf about these matters:

SEE ATTACHMENT A

Place:	Date and Time:
TransPerfect Legal Solutions 1111 Superior Ave E., Suite 1400 Cleveland, OH 44114	08/10/2023 10:00 am

The deposition will be recorded by this method: Stenographically, audiotaped, and videotaped

☑ *Production:* You, or your representatives, must also bring with you to the deposition the following documents, electronically stored information, or objects, and must permit inspection, copying, testing, or sampling of the material:

See Schedule A (attached). Documents to be produced on or before July 21, 2023, to:
Jamie Kringstein, Desmarais LLP, 230 Park Avenue, New York, NY 10169
jkringstein@desmaraisllp.com

The following provisions of Fed. R. Civ. P. 45 are attached – Rule 45(c), relating to the place of compliance; Rule 45(d), relating to your protection as a person subject to a subpoena; and Rule 45(e) and (g), relating to your duty to respond to this subpoena and the potential consequences of not doing so.

Date: 07/06/2023

CLERK OF COURT

OR

/s/ Jamie L. Kringstein

Signature of Clerk or Deputy Clerk *Attorney's signature*

The name, address, e-mail address, and telephone number of the attorney representing *(name of party)* Plaintiff Apple Inc. , who issues or requests this subpoena, are:

Jamie Kringstein | Desmarais LLP | 230 Park Ave., New York, NY 10169 | 212-808-2921 | jkringstein@desmaraisllp.com

Notice to the person who issues or requests this subpoena

If this subpoena commands the production of documents, electronically stored information, or tangible things before trial, a notice and a copy of the subpoena must be served on each party in this case before it is served on the person to whom it is directed. Fed. R. Civ. P. 45(a)(4).

Civil Action No. 22-cv-1378-MN-JLH

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 45.)

I received this subpoena for *(name of individual and title, if any)* ______________________
on *(date)* __________ .

❒ I served the subpoena by delivering a copy to the named individual as follows: ______________
____
______________________________ on *(date)* __________ ; or

❒ I returned the subpoena unexecuted because: ______________________
____ .

Unless the subpoena was issued on behalf of the United States, or one of its officers or agents, I have also tendered to the witness the fees for one day's attendance, and the mileage allowed by law, in the amount of
$ __________ .

My fees are $ __________ for travel and $ __________ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: __________ ______________________________

Server's signature

____

Printed name and title

____

Server's address

Additional information regarding attempted service, etc.:

Federal Rule of Civil Procedure 45 (c), (d), (e), and (g) (Effective 12/1/13)

(c) Place of Compliance.

(1) ***For a Trial, Hearing, or Deposition.*** A subpoena may command a person to attend a trial, hearing, or deposition only as follows:
(A) within 100 miles of where the person resides, is employed, or regularly transacts business in person; or
(B) within the state where the person resides, is employed, or regularly transacts business in person, if the person
(i) is a party or a party's officer; or
(ii) is commanded to attend a trial and would not incur substantial expense.

(2) ***For Other Discovery.*** A subpoena may command:
(A) production of documents, electronically stored information, or tangible things at a place within 100 miles of where the person resides, is employed, or regularly transacts business in person; and
(B) inspection of premises at the premises to be inspected.

(d) Protecting a Person Subject to a Subpoena; Enforcement.

(1) ***Avoiding Undue Burden or Expense; Sanctions.*** A party or attorney responsible for issuing and serving a subpoena must take reasonable steps to avoid imposing undue burden or expense on a person subject to the subpoena. The court for the district where compliance is required must enforce this duty and impose an appropriate sanction—which may include lost earnings and reasonable attorney's fees—on a party or attorney who fails to comply.

(2) ***Command to Produce Materials or Permit Inspection.***
(A) *Appearance Not Required.* A person commanded to produce documents, electronically stored information, or tangible things, or to permit the inspection of premises, need not appear in person at the place of production or inspection unless also commanded to appear for a deposition, hearing, or trial.
(B) *Objections.* A person commanded to produce documents or tangible things or to permit inspection may serve on the party or attorney designated in the subpoena a written objection to inspecting, copying, testing, or sampling any or all of the materials or to inspecting the premises—or to producing electronically stored information in the form or forms requested. The objection must be served before the earlier of the time specified for compliance or 14 days after the subpoena is served. If an objection is made, the following rules apply:
(i) At any time, on notice to the commanded person, the serving party may move the court for the district where compliance is required for an order compelling production or inspection.
(ii) These acts may be required only as directed in the order, and the order must protect a person who is neither a party nor a party's officer from significant expense resulting from compliance.

(3) ***Quashing or Modifying a Subpoena.***

(A) *When Required.* On timely motion, the court for the district where compliance is required must quash or modify a subpoena that:

(i) fails to allow a reasonable time to comply;
(ii) requires a person to comply beyond the geographical limits specified in Rule 45(c);
(iii) requires disclosure of privileged or other protected matter, if no exception or waiver applies; or
(iv) subjects a person to undue burden.
(B) *When Permitted.* To protect a person subject to or affected by a subpoena, the court for the district where compliance is required may, on motion, quash or modify the subpoena if it requires:
(i) disclosing a trade secret or other confidential research, development, or commercial information; or
(ii) disclosing an unretained expert's opinion or information that does not describe specific occurrences in dispute and results from the expert's study that was not requested by a party.
(C) *Specifying Conditions as an Alternative.* In the circumstances described in Rule 45(d)(3)(B), the court may, instead of quashing or modifying a subpoena, order appearance or production under specified conditions if the serving party:
(i) shows a substantial need for the testimony or material that cannot be otherwise met without undue hardship; and
(ii) ensures that the subpoenaed person will be reasonably compensated.

(e) Duties in Responding to a Subpoena.

(1) ***Producing Documents or Electronically Stored Information.*** These procedures apply to producing documents or electronically stored information:
(A) *Documents.* A person responding to a subpoena to produce documents must produce them as they are kept in the ordinary course of business or must organize and label them to correspond to the categories in the demand.
(B) *Form for Producing Electronically Stored Information Not Specified.* If a subpoena does not specify a form for producing electronically stored information, the person responding must produce it in a form or forms in which it is ordinarily maintained or in a reasonably usable form or forms.
(C) *Electronically Stored Information Produced in Only One Form.* The person responding need not produce the same electronically stored information in more than one form.
(D) *Inaccessible Electronically Stored Information.* The person responding need not provide discovery of electronically stored information from sources that the person identifies as not reasonably accessible because of undue burden or cost. On motion to compel discovery or for a protective order, the person responding must show that the information is not reasonably accessible because of undue burden or cost. If that showing is made, the court may nonetheless order discovery from such sources if the requesting party shows good cause, considering the limitations of Rule 26(b)(2)(C). The court may specify conditions for the discovery.

(2) ***Claiming Privilege or Protection.***
(A) *Information Withheld.* A person withholding subpoenaed information under a claim that it is privileged or subject to protection as trial-preparation material must:
(i) expressly make the claim; and
(ii) describe the nature of the withheld documents, communications, or tangible things in a manner that, without revealing information itself privileged or protected, will enable the parties to assess the claim.
(B) *Information Produced.* If information produced in response to a subpoena is subject to a claim of privilege or of protection as trial-preparation material, the person making the claim may notify any party that received the information of the claim and the basis for it. After being notified, a party must promptly return, sequester, or destroy the specified information and any copies it has; must not use or disclose the information until the claim is resolved; must take reasonable steps to retrieve the information if the party disclosed it before being notified; and may promptly present the information under seal to the court for the district where compliance is required for a determination of the claim. The person who produced the information must preserve the information until the claim is resolved.

(g) Contempt.
The court for the district where compliance is required—and also, after a motion is transferred, the issuing court—may hold in contempt a person who, having been served, fails without adequate excuse to obey the subpoena or an order related to it.

For access to subpoena materials, see Fed. R. Civ. P. 45(a) Committee Note (2013).

ATTACHMENT A

SCHEDULE A

DEFINITIONS

The following terms shall have the meanings set forth below whenever used in any Definition, Instruction, Request for Production, or Deposition Topic.

1. As used herein, the terms "Sotera," "You," or "Your" means Sotera, Inc., Sotera Wireless, Inc., and all of their predecessors (merged, acquired, or otherwise), successors, subsidiaries, divisions, departments, and affiliates thereof, and all officers, directors, principals, agents, employees, attorneys, and other persons acting on their behalf.

2. As used herein, "Apple" means Apple Inc., all of its predecessors (merged, acquired, or otherwise), successors, subsidiaries, divisions, departments, and affiliates thereof, and all officers, directors, principals, agents, employees, attorneys, and other persons acting on their behalf.

3. As used herein, "Masimo" means Masimo Corporation, Cercacor Laboratories, Inc., and all their predecessors (merged, acquired, or otherwise), successors, subsidiaries, parents, sisters, divisions, departments, partnerships, and affiliates thereof, and all of their officers, directors, principals, agents, employees, independent contractors working under their control, attorneys, and other persons acting on their behalf.

4. As used herein, "Masimo Asserted Patents" means U.S. Patent No. 10,687,743 ("the '743 Patent"), U.S. Patent No. 10,722,159 ("the '159 Patent"), U.S. Patent No. 8,190,223 ("the '223 Patent"), U.S. Patent No. 10,736,507 ("the '507 Patent"), and U.S. Patent No. 10,984,911 ("the '911 Patent").

5. As used herein, "Relevant Date" means September 20, 2012.

6. As used herein, "Exhibits" means Exhibits 1-3 attached hereto.

7. As used herein, "Blood Oxygen and Heart Rate Features" means the product feature(s) relating to monitoring, measuring, sensing, detecting, and/or obtaining blood oxygen (SpO2) and/or heart rate measurements, including all hardware, software, firmware, components, modules, applications, and devices involved in such features, that were made or sold before the Relevant Date.

8. As used herein, "Product" means any machine, manufacture, apparatus, device, system, process, service, method, or instrumentality which is designed to function together electrically, mechanically, chemically, or otherwise, to achieve a particular function or purpose, including those offered for sale, sold, imported, or under development.

9. As used herein, "Relevant Products" means (1) the Sotera ViSi Mobile Monitoring System, (2) the ViSi Mobile Monitor, (3) the ViSi Mobile Thumb Sensor, (4) the ViSi Mobile Cuff Module, (5) the ViSi Mobile Chest Sensor Cable, (6) the ViSi Mobile Wrist Strap, (7) the ViSi Mobile Wrist Cradle, (8) any Sotera ViSi Mobile Software, (9) any ViSi Mobile Remote Viewer software, (10) the products described in Exhibits 1-3, (11) any Product made or sold by or for You having Blood Oxygen and Heart Rate Features before the Relevant Date, (12) any related Products or modules having Blood Oxygen and Heart Rate Features before the Relevant Date, and (13) any other software programs, applications, or modules that display Blood Oxygen or Heart Rate from the Relevant Products.

10. As used herein, "Source Code" means any human-readable programming language or format that defines software, firmware or integrated circuits, including but not limited to, computer code, scripts, assembly, binaries, object code, Register Transfer Level ("RTL") descriptions, VHDL, Verilog, and other Hardware Description Language ("HDL") formats.

11. The term "Third Party" means any person or entity other than You, Masimo, or Apple.

12. As used herein, the term "document" shall have the full meaning ascribed to it by the Federal Rules of Civil Procedure and includes the original and every non-identical copy or reproduction in Your possession, custody, or control, and further is used in a broad sense to refer to any electronically stored information ("ESI") or any tangible object or thing that contains, conveys, or records information.

13. As used herein, the singular of any word shall include the plural, and the plural shall include the singular.

14. As used herein, "person" means any natural person or any business, legal, or governmental entity or association.

15. As used herein, "include" and "including" shall be construed to mean "without limitation," so as to give the broadest possible meaning to interrogatories and definitions containing those words.

16. As used herein, "and" and "or" shall be construed conjunctively and disjunctively so as to acquire the broadest meaning possible.

17. As used herein, "any" and "all" shall each be construed to mean "each and every," so as to acquire the broadest meaning possible.

18. As used herein, the singular of any word shall include the plural, and the plural shall include the singular.

19. As used herein, "related" or "relating" to any given subject means, without limitation, identifying, describing, discussing, concerning, assessing, stating, reflecting

constituting, containing, embodying, tending to support or refute, or referring directly or indirectly to, in any way, the particular subject matter identified.

20. As used herein, "identify" as applied to a document shall mean to specify: (a) the type of the document (i.e., whether it is a letter, memorandum, e-mail, etc.); (b) the document's title and general subject matter; (c) the number of pages of the document; (d) the date the document was prepared; (e) the name of each and every author, addressee, distributor, and recipient of the document; (f) the date each distributor distributed the document and the date each recipient received the document; and (g) the name of each person that has or had possession, custody, or control of the document.

21. Any term not specifically defined herein shall be defined in accordance with normal usage as well as with the Federal Rules of Civil Procedure and the Local Rules of the United States District Court for the District of Delaware.

INSTRUCTIONS FOR REQUESTS FOR PRODUCTION

1. Apple's Requests for Production seek responsive documents and information sufficient to answer each of the Requests that are known or available You or in Your possession, custody, or control. If, after exercising due diligence to secure the documents or information requested, You cannot fully respond to a Request for Production, state that such is the case and answer to the fullest extent possible, stating what responsive documents or information are available, what documents or information cannot be provided, why the documents or information are unavailable, and what efforts were made to obtain the unavailable documents or information. If documents or information responsive to a Request in this subpoena are in Your control, but not in Your possession or custody, promptly identify the entity with possession or custody.

2. Regardless of whether a production is in electronic or paper format, documents that were maintained together before production should be produced in the same form, sequence, organization, or other order or layout as they were maintained, including any labels, file folders, file jackets, covers, or containers in which such documents are located or with which such documents are associated. If copies of documents are produced in lieu of the originals, such copies should be legible and bound or stapled in the same manner as the original.

3. These Requests for Production shall be deemed continuing. Documents located, and information learned or acquired, at any time after Your response is due must be promptly supplemented at the place specified in this subpoena.

4. A copy of the Protective Order entered in this Action for the protection of any requested proprietary, confidential, or commercially sensitive information is attached hereto.

REQUESTS FOR PRODUCTION

1. Documents sufficient to identify and describe the functionality, features, and operation of the Blood Oxygen and Heart Rate Features of the Relevant Products and all components, modules, applications, hardware, software, and firmware contained therein, including, without limitation, user manuals, brochures, presentations, user guides, product literature, engineering specifications, circuit diagrams, architectural diagrams, bills of materials, technical manuals, product specifications, data sheets, laboratory notebooks, research papers, test data and results, analyses, invention disclosure forms, reports, service manuals, operator's manuals, implementation guides, white papers, product tutorials, and non-public documentation.

2. Documents sufficient to identify and describe the conception, design, research, development, testing, use, operation, maintenance, marketing, modifying, sale, offer for sale, and supply of the Relevant Products, including the persons and entities involved.

3. Documents, communications, and things comparing the Apple Watch to the Relevant Products.

4. Other versions of the Exhibits and documentation related to the Exhibits.

5. Documents sufficient to show the earliest dates that each of the Relevant Products were first conceived; reduced to practice; and made, sold, used (including by third parties such as end users), offered for sale, in public use, and otherwise available to the public in the United States, including but not limited to documents relating to any conference, seminar, exhibition, convention, or trade show at which such Product is or was discussed, referred to, advertised, displayed, demonstrated, or shown, such as, without limitation, product specifications, catalogs, announcements, advertisements, brochures, articles, pamphlets, price lists, invoices, purchase orders, sales records, or other promotional, marketing, or sales materials.

6. Publications related to the Relevant Products that were made available to the public.

7. Three samples of each Relevant Product.

8. Source Code sufficient to show the functionality of the Blood Oxygen and Heart Rate Features of the Relevant Products.

9. Documents relating to any contention by Masimo that any Relevant Product meets any claim of any Masimo patent, including but not limited to Masimo's infringement contentions for U.S. Patent Nos. 9,788,735, 9,795,300, 9,872,623, 10,213,108, and 10,255,994 in *Masimo Corporation v. Sotera Wireless, Inc., et al.*, 19-cv-1100-BAS-NLS (S.D. Cal. 2020).

10. Documents sufficient to show the authorship and authenticity of all the documents produced in response to this subpoena.

DEPOSITION TOPICS

1. The functionality, features, and operation of the Blood Oxygen and Heart Rate Features of the Relevant Products.

2. The earliest dates that each Relevant Product was reduced to practice, made, sold, offered for sale, in public use, or otherwise available to the public.

3. The subject matter contained within the documents produced in response to Requests For Production herein, including the authentication thereof.

4. The authorship and authenticity of the documents produced in response to the Requests For Production herein.

EXHIBIT 1

ViSi Mobile® is a comprehensive monitoring system, designed to enhance patient safety, allowing early detection of patient deterioration and connecting clinicians with their patients anywhere, any time.

Refer to the ViSi Mobile User Documentation [REF: 95-10134]
for Indications for Use, Contraindications, Warnings, Precautions, Description, Set-up, and Operation.

PATIENT-WORN DEVICES		SPECIFICATIONS
VISI MOBILE MONITOR  [REF 92-10010]	*Dimensions* 2.6 cm H x 4.9 cm W x 9.4 cm L 1.0 in H x 1.9 in W x 3.7 in L *Monitor / Display* OLED, 160 x 128 pixels, full color, capacitive touch screen *Waveforms* One waveform, user selectable (ECG, Pleth, Resp) *Battery* Battery Type Li-Ion, 3.7 V., 2000 mAh, single cell Operating Time 12-24 hours (depending on use profile) Charge Time Less than 4 hours *Liquid Ingress Rating:* IPX7	*Weight* 110 g 3.9 oz *Audio:* Alarm annunciation (72dBA), QRS beep, Self-Test ***Wireless Connectivity*** *Network Standard:* IEEE 802.11b, 11 and 5.5 Mbps *Antenna Gain:* 1.0 dB *Traffic generated (one Monitor):* Less than 20 KBps (Numerics, Trends, Events, Waveforms) *Wireless Network Security Support:* WPA2-PSK *Network Protocol:* TCP/IP WiFi
VISI MOBILE CUFF MODULE  [REF 92-10011]	*Dimensions* 3.1 cm H x 4.9 cm W x 12.2 cm L 1.2 in H x 1.9 in W x 4.8 in L *Display* Eight LEDs: Six Green, One Yellow, One Red LEDs in array showing charge levels of onboard battery *Battery* Battery Type Li-Ion, 3.7 V., 2000 mAh, single cell > 30 cuff inflations Charge Time Less than 4 hours	*Weight* 157 g 5.5 oz *Audio* None
VISI MOBILE CHEST SENSOR  3-lead [REF 93-10014] 5-lead[REF 93-10012]	*Dimensions* 152.4 cm L 60.0 in L *Liquid Ingress Rating:* IPX7	*Weight* 5-LEAD-WIRE: 72 g, 2.5 oz 3-LEAD WIRE: 62 g, 2.2 oz
VISI MOBILE THUMB SENSOR  [REF 92-10020]	*Dimensions* 22.5 cm L 8.9 in L *Liquid Ingress Rating:* IPX7	*Weight* 8 g 0.3 oz

ACCESSORIES		SPECIFICATIONS
VISI MOBILE BATTERY CHARGER [8 POSITION]  **[REF 92-10023]**	Charges up to eight ViSi Mobile Monitors / Cuff Modules *Dimensions* 7.6 cm H x 6.0 cm W x 47.0 cm L 3.0 in H x 2.4 in. W x 18.5 in L *(exclusive of power supply & cable)* *Power Input:* AC Adapter, Input: 100-240V, 50-60Hz *Liquid Ingress Rating:* IPX0	*Weight* 670 g 1lb 7 oz *(exclusive of power supply & cable)*

ACCESSORIES / SPECIFICATIONS

VISI MOBILE BATTERY CHARGER [2 POSITION]

[REF 92-10022]

Charges up to two ViSi Mobile Monitors / Cuff Modules
Dimensions
7.6 cm H x 6.0 cm W x 12.7 cm L
3.0 in H x 2.4 in W x 5.0 in L
(exclusive of power supply & cable)
Power Input: AC Adapter, Input: 100-240V 50-60Hz
Liquid Ingress Rating: IPX0

Specifications:
Weight
240 g
8.3 oz
(exclusive of power supply & cable)

MODE PLUGS

Plug into ViSi Mobile Monitor to:
Turn device off completely: *Shipping Plug [REF: 99-10025]*
Secure Monitor into Wrist Cradle when not using Thumb Sensor, e.g. monitoring ECG only: *Locking Plug [REF 99-10026]*

VISI MOBILE PATIENT KIT (DISPOSABLE)

[S: REF 92-10066]
[M: REF 92-10067]
[M+: REF 92-10070]
[L: REF 92-10068]
[L+: REF 92-10069]

Contains all disposable components to set-up one individual patient, interchangeable left or right arm

Kit Components
Wrist Cradle incl. strap – holds ViSi Mobile Monitor on patient's wrist

Thumb Cradle – holds ViSi Mobile Thumb Sensor on patient's thumb

Welch Allyn Flexiport™ Disposable Blood Pressure Cuff – with ViSi Mobile Cuff Module adaptor

Cable Securement packet – secures Chest Sensor modules to patient (chest and upper arm)

Five (5) Pre-Packaged 3M Disposable ECG Electrodes

Specifications:
Sizing: Relevant to the Blood Pressure Cuff and the Wrist Cradle strap. All other components are one-size-fits-all.

Wrist Strap Sizes - Wrist Circumference Ranges

Small	4 ½-6 in.	11.4-15.2 cm
Medium	5-7 in.	12.7-17.8 cm
Large	6-10 in.	15.2-25.4 cm

Blood Pressure Cuffs Sizes - Arm Circumference Ranges (follows Welch Allyn FlexiPort™ cuff sizing)

Small (10)	7.9-10.2 in.	20-26 cm
Medium (11)	9.8-13.4 in.	25-34 cm
Medium+ (11L)	9.8-13.4 in.	25-34 cm
Large (12)	12.6-16.9 in.	32-43 cm
Large+ (12L)	12.6-16.9 in.	32-43 cm

VITAL SIGNS MEASUREMENTS / SPECIFICATIONS

ECG HEART RATE

Display Range: 0 to 240 BPM
Resolution: 1 BPM
Pacemaker: Detects and rejects pacemaker impulses in accordance with ANSI/AAMI EC13:2002
- Displays pacer markers on ECG waveforms
Sampling: 500Hz sampling, 19bit resolution
Defibrillation Response / Protection
- Displays an ECG waveform < 10 seconds after a defibrillation event
- Displays HR measurement < 30 seconds after a defibrillation event

Specifications:
Accuracy Range: 30 to 240 BPM
Accuracy: 3BPM ±3% of reading
Heart Rate Averaging: 10 second moving average
3-Lead : Lead II
5-Lead: Leads I, II, III, aVR, aVL, aVF, and a V lead
Factory default alarm threshold: High 200 BPM / Low 30 BPM
Audio Alarm Delay: 1 sec

RESPIRATION

Method: Impedance Pneumography
Display Range: 0 to 50 BR/MIN
Resolution: 1 BR/MIN

Specifications:
Accuracy Range: 3 to 50 BR/MIN
Accuracy: ±3 BR/MIN or 10% of reading, whichever is greater
Factory default alarm threshold: High 40 / Low 4
Audio Alarm Delay: 60 seconds on care unit alarm limits, 120 seconds on patient alarm limits

VITAL SIGNS MEASUREMENTS		SPECIFICATIONS
PULSE OXIMETRY (SPO2, PULSE RATE)	***SpO2*** *Display Range:* 49 to 100% *Accuracy Range:* 70 to 100% *Accuracy (no motion):* ≤ 2% from 70-100% / unspecified from 49-69% *Resolution: 1%* *Averaging:* Adaptive 30 second moving average *Factory default alarm threshold:* Low 85% *Audio Alarm delay:* 30 seconds	***Pulse Rate (from Oximetry)*** *Display Range:* 0 to 240 BPM *Accuracy Range:* 30 to 240 BPM *Accuracy:* ± 3 BPM; < 50 BPM @ ≥ 0.6% Pulsatile Modulation / ≥ 50 BPM @ ≥ 0.4% Pulsatile Modulation *Resolution: 1BPM* *Averaging:* Adaptive 30 second moving average *Factory default alarm threshold:* High 200 / Low 30 *Audio Alarm delay:* 30 seconds
NON-INVASIVE BLOOD PRESSURE (NIBP)	***NIBP*** *Method:* Oscillometry *Accuracy & Display Range:* 60 to 240 mmHg (SYS), 40 to 160 mmHg (DIA), 50 to 185 mmHg (MAP) *Accuracy:* Mean error of less than ± 5 mmHg and a standard deviation of ≤ 8 mmHg *Resolution:* 1 mmHg *Mode of Operation* Manual mode – Single NIBP, max. 3 tries Automatic mode – NIBP taken automatically every 5, 10, 15, 30, 60, 90 or 120 minutes.	***Pulse Rate (from Oscillometry)*** *Display Range:* 0 to 240 BPM *Accuracy Range:* 30 to 240 BPM *Accuracy:* ± 3 BPM; < 50 BPM @ ≥ 0.6% Pulsatile Modulation / ≥ 50 BPM @ ≥ 0.4% Pulsatile Modulation *Resolution: 1BPM*
CONTINUOUS NON-INVASIVE BLOOD PRESSURE (CNIBP)	***cNIBP*** *Method:* Based on Pulse Arrival Time *Accuracy & Display Range:* 60 to 240 mmHg (SYS), 40 to 160 mmHg (DIA), 50 to 185 mmHg (MAP) *Accuracy:* Mean error of less than ± 5 mmHg and a standard deviation of ≤ 8 mmHg *Resolution:* 1 mmHg Averaging: 60 seconds *Mode of Operation* Initial calibration required with ViSi Mobile Cuff Module	

TEMPERATURE (SKIN)

(at 102 kPa / 768 mmHg atmospheric pressure)

°Centigrade		°Fahrenheit	
Accuracy Range	*Accuracy*	*Accuracy Range*	*Accuracy*
0.0° - 19.9°	±0.3°	32.0° - 67.9°	±0.5°
20.0° - 24.9°	±0.3°	68.0° - 76.9°	±0.5°
25.0° - 35.9°	±0.2°	77.0° - 96.7°	±0.3°
36.0° - 39.9°	±0.1°	96.8° - 103.9°	±0.2°
40.0° - 41.9°	±0.2°	104.0° - 107.5°	±0.3°
42.0° - 50.0°	±0.3°	107.6° - 122.0°	±0.5°
Resolution: ± 0.1°		*Resolution:* ± 0.1°	
***Transient Response:* < 6 min (25.0° – 37.0°)**		***Transient Response:* < 6 min (77.0° - 98.6°)**	

SYSTEM COMPONENTS *[ALL SYSTEM COMPONENTS ARE PROVIDED, IMPLEMENTED AND CONFIGURED BY SOTERA WIRELESS]*

APPLIANCE	*Standard Server Configuration* Single 1u, redundant hardware and internal RAID 10, dedicated hardware *Processor:* Single Intel Xeon 5620, 2.4 GHz, (or equivalent CPU), 8GB memory *Storage:* Server contains (4) 500GB 7200 RPM Hard drives in RAID 10 array *Operating System* SUSE Linux Enterprise Server 11 Service Pack 2 *Network Requirements* Static IP address or DHCP reservation required Multicast configuration on network backbone devices *Dimensions (single appliance, may vary):* 4.3 cm H x 43.4 cm W x 62.7 L cm (w/o ear, w/o bezel) 1.7 in H x 17.1 in W x 24.7 L *Weight (single appliance):* 35.0 lbs (15.9 kg) [Maximum configuration weight] *Power Requirements (single appliance):* w/Redundant Power supply 100-240 VAC, 50-60 Hz, 7A-3.5A *Backup Power Requirement (full system):* Customer supplied Uninterruptable Power Supply required, Hospital Emergency Power recommended **** This configuration is only recommended for systems of less than 32 ViSi Mobile Monitors, and if high-availability is not required and downtime for SW update is acceptable*	*High-Availability Server Configuration* Dual 1u load balanced, redundant hardware and external SAN in RAID 10 configuration*, dedicated hardware.* *Processor:* Single Intel Xeon 4 core E5620, 2.4 GHz (or equivalent CPU) in each server, 8GB memory *Storage:* Each Server in the cluster contains (1) 500 GB 7200 RPM Hard Drive to support the operating system SAN: 2u chassis houses (6) 1TB 7200 RPM hard drives in RAID 10 configuration, connected to both servers via iSCSI, can be expanded *Operating System* SUSE Linux Enterprise Server 11 patch 2 *Network Requirements* Static IP address or DHCP reservation required Multicast configuration on network backbone devices *Dimensions (single appliance, may vary):* 4.3 cm H x 43.4 cm W x 62.7 cm L (w/o ear, w/o bezel) 1.7 in H x 17.1 in W x 24.7 L *Weight (single appliance):* 35.0 lbs (15.9 kg) [Maximum configuration weight] *Power Requirements (single appliance):* w/Redundant Power supply 100-240 VAC, 50-60 Hz, 7A *Backup Power Requirement (full system):* Customer supplied dual Uninterruptable Power Supply required, Hospital Emergency Power recommended *SAN Dimensions (may vary):* 8.7 cm H x 43.4 cm W x 62.7 cm L 3.4 in H x 17.6 in W x 20.0 in L *SAN Weight (may vary):* 53.4 lbs (24.2 kg) [Maximum configuration weight] *SAN Power Requirements:* 100-240 VAC, 50-60 Hz, 5.5A *Future Release. Appliance sizing and drive configuration depends on number of ViSi Mobile Monitors and the length of time the healthcare facility is required to retain vital sign data.* *** The high availability configuration minimizes unplanned downtime due to hardware failures and supports live service while periodic application upgrades occur.*

	Recommended	Alternate
Remote Viewer (Stationary)	*Desktop PC - Touchscreen Display* All-in-One configuration *# Patients per Remote Viewer:* Max. 32 *Display:* 23-inch display, 1920x1080 resolution *(screen is touch sensitive to issue commands alternative to mouse / keyboard)* *Processor* Intel i5 2400 CPU 4 Core, 3.10GHz, 4Gb Memory *Storage* One 500GB 7200RPM SATA *Operating System:* Windows 7 Professional x64 Bit SP1 *Network Requirements:* Ethernet Connection, DHCP *Dimensions:* 45.0 cm H x 58.5 cm W x 10.3 cm D 17.7 in H x 23.0 in W x 4.1 in D *Weight:* 26.7 lb (12.1 kg) *Power Requirements:* AC/DC Adapter, Input: 100-240V~3.5A, 50-60Hz, Output to Viewer: 19.5V/ 11.8A *Backup Power Requirement:* Customer supplied Uninterruptable Power Supply and Hospital Emergency Power recommended	*Desktop PC - Standard Display (not touch sensitive)* All-in-One configuration *# Patients per Remote Viewer:* Max. 32 *Display:* 23-inch display, 1920x1080 resolution *(screen is not touch sensitive and commands are issued using a mouse / keyboard)* *Processor* Intel i5 2400s CPU 4 Core, 2.5GHz, 4Gb Memory *Storage* One 500GB 7200RPM SATA *Operating System:*Windows 7 Professional x64 Bit SP1 *Network Requirements:* Ethernet Connection, DHCP *Dimensions:* 47.2 cm H x 58.4 cm W x 22.0cm D 18.6 in H x 23.0 in W x 8.7 in D *Weight:* 18.7 lb (8.5 kg) *Power Requirements:* AC/DC Adapter, Input: 100-240V~2A, 50-60Hz, Output to Viewer: 19V / 7.9A *Backup Power Requirement:* Customer supplied Uninterruptable Power Supply and Hospital Emergency Power recommended

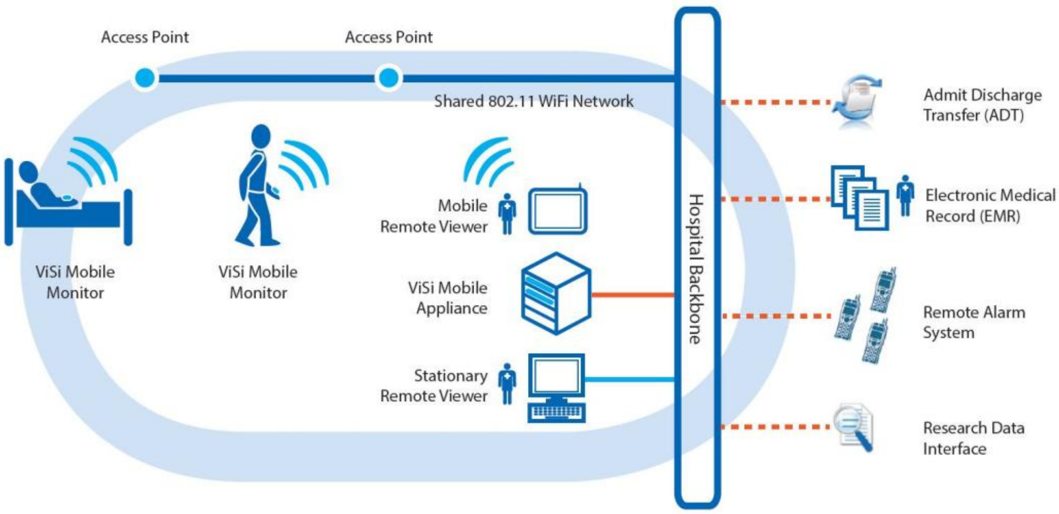
Customer Network *[Network to be implemented and managed by end user in accordance with IEC 80001-1]*

	Wireless Network *Wireless Network Standard:* IEEE 802.11b *Network latency:* <150ms *Wireless Network Security Support:* WPA2-PSK *Minimum Receiver Sensitivity*: -65dBm (edge coverage) *Wireless access point cell overlap:* 15-20% *Signal-to-Noise Ratio:* ≥ 25 db *Packet loss:* ≤6% *SSID:* Dedicated or shared with other medical devices	*Wired Network* *Appliance (Server):* requires Static IP Address *Network availability:* >99.99%

Agency Compliance

	ANSI/AAMI: Cardiac monitors, heart rate meters, and alarms EC53, ECG cables and lead wires. ***ISO:*** 9919, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximetry equipment for medical use. 81060-2, Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type.	***IEC:*** 60601-1, Medical electrical equipment - Part 1: General requirements for safety 60601-1-2, Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: EMC–Req. and tests. 60601-1-8, Medical electrical equipment – Part 1-8: General requirements – Collateral standard: General requirements, tests and guidance for alarm systems in medical electrical equipment and medical electrical systems. 60601-2-27, Medical electrical equipment - Part 2-27: Particular requirements for the basic safety and essential performance of electrocardiographic monitoring equipment.60601-2-49, Particular requirements for the safety of multifunction patient monitoring equipment. 80601-2-30, Medical electrical equipment – Part 2-30: particular requirements for the safety, including essential performance, of auto-cycling NIBP monitoring equipment.

VISI MOBILE SYSTEM ARCHITECTURE



The ViSi Mobile System has received CE mark and is currently FDA cleared for continuous monitoring of ECG, Heart/Pulse Rate, SpO_2, Blood Pressure (cuff-based and cuffless on a beat-to-beat basis), Respiration Rate and Skin Temperature. Posture/Activity is in final stages of development and is not yet cleared.

For questions please call +1 (866) 794-5526 (from US) or +1 (858) 373-4870 (from intl.), email Support@SoteraWireless.com or visit www.SoteraWireless.com

Sotera WIRELESS

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www.soterawireless.com

EXHIBIT 2

Monitoring System
Technical Reference Manual

July 2015

Reference Number (USB): 95-10134

Part Number: 6-000147-06

10020 Huennekens Street
San Diego, California 92121 USA

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EC REP

Australian Sponsor

EMERGO EUROPE
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The Hague
The Netherlands

EMERGO AUSTRALIA Level
20, Tower II Darling Park 201
Sussex Street
Sydney, NSW 2000
Australia

For additional information or assistance, please contact Sotera Wireless, Inc. or an authorized Sotera Wireless, Inc. representative in your area.

CE 0297

Information for servicing the ViSi Mobile Monitoring System is contained in the ViSi Mobile Monitoring System Technical Manual, Part Number: 6-000147. For additional information or assistance, please contact Sotera Wireless or an authorized Sotera Wireless representative in your area.

Contents

1. Preface

1.1 Introduction

This ViSi Mobile Technical Reference Manual is intended to provide information for the care of the ViSi Mobile Monitoring System. This manual is intended to be used by qualified hospital personnel.

Do not operate the ViSi Mobile Monitoring System before reading these instructions.

Bio Meds must complete training by Sotera Wireless, Inc. before utilizing any of these functions.

1.2 Intended Use

The ViSi Mobile Monitoring System is intended for use by clinicians and medically qualified personnel for single or multi-parameter vital signs monitoring of adult patients. It is indicated for ECG (3 or 5 lead wire), respiration rate, heart rate, non-invasive blood pressure (NIBP), non-invasive monitoring of functional oxygen saturation of arterial hemoglobin (SpO_2), pulse rate, and skin temperature in hospital-based facilities; including general medical-surgical floors, intermediate care floors, and emergency departments.

The ViSi Mobile Monitoring System may be used as standalone devices or networked to a ViSi Mobile Remote Viewer through wireless 802.11 communication.

1.2.1 Contraindications

- Impedance pneumography for the determination of Respiration Rate (RESP) is not recommended for use in the presence of mechanically induced high frequency ventilation.
- The ViSi Mobile Monitoring System has not been tested for use on neonatal or pediatric patients under the age of 18 years.
- Do not use the same ViSi Mobile Monitor System to measure the NIBP of one patient while it is connected simultaneously to another patient.
- Do not use the ViSi Mobile Monitor on a patient with an Intra-Aortic Balloon Pump (IABP), or a Left Ventricular Assist Device (LVAD). The Monitor requires an unperturbed arterial pulse waveform for non-invasive blood pressure calculations. IABP and LVAD perturb the arterial pulse waveform.
- Do not use the ViSi Mobile Monitor System on a patient on cardio-pulmonary bypass.
- Do not use the ViSi Mobile Cuff Module on a patient's arm where the use of a blood pressure cuff is contraindicated.
- Do not use the ViSi Mobile Monitoring System in an MRI Suite.
- The effectiveness of the ViSi Mobile Monitoring System's blood pressure monitoring has not been established in the presence of any dysrhythmias.

2. ViSi Mobile Warnings and Cautions

2.1 Introduction

Please read and adhere to all warnings, cautions and notes listed here and in the associated sections throughout this manual.

Do not operate the ViSi Mobile Monitoring System before reading these instructions.

Warning statements alert the user to conditions or practices that could result in injury to a person, or serious adverse events associated with the use or misuse of the ViSi Mobile Monitoring System.

Caution statements alert the user to conditions or practices that could result in problems with the ViSi Mobile Monitoring System associated with its use or misuse.

Note: Statements provide supplemental information to the user.

2.2 Warnings ⚠

Intended Use

Do not use the ViSi Mobile Monitoring System or Power Pack outside the intended use described in this manual. Doing so can result in a delay in or inappropriate therapy.

Do not use the ViSi Mobile Monitoring System in neonatal or pediatric patients (under the age of 18 years) since the System has not been evaluated for these patient groups.Do not use the ViSi Mobile Monitor as a primary hypoxia diagnostic tool.

Safety

The ViSi Power Pack is not intended to be worn by the patient.

Do not modify the ViSi System in any way.

Do not use the ViSi Mobile Monitor, Cuff Module, Chest Sensor or Power Pack in an MRI suite or a hyperbaric chamber.

The ViSi System is protected against damage from electrosurgery. Avoid electrosurgery burns at the ECG monitoring sites by ensuring the electrosurgery-return circuit is connected properly and monitoring electrodes are located as far as possible from the electrosurgery site.

Monitoring may be temporarily interrupted during the use of electrosurgery in the vicinity of/or on a patient being monitored with a ViSi Mobile Monitoring System. Observe the patient closely while electrosurgery is in use.

To ensure patient safety, use only components and accessories recommended or supplied by Sotera Wireless, Inc. Accessories must always be used in accordance with your facility's policies and the manufacturer's recommendations.

Use only the AC adapter recommended for the ViSi Mobile Charger. Use of other AC adapters may result in damage to the unit.

Do not connect more than one ViSi Power Pack to the ViSi Mobile Monitor simultaneously.

The ViSi Mobile Monitoring System has not been tested in the presence of flammable anesthetics or other flammable agents in combination with air, nitrous oxide, or oxygen-enriched environments.

Route all ViSi Mobile Monitoring System cabling to avoid the possibility of patient entanglement or strangulation.

Warnings ⚠

To ensure patient safety, the conductive parts of the ECG electrodes, including connectors and other patient-applied components, should not contact other conductive parts, or earth ground, at any time.

Never connect the ViSi Mobile Chest Sensor directly to an AC power outlet.

Never connect the ViSi Mobile Cuff Module directly to an AC power outlet. To recharge the battery, disconnect the Cuff Module from the patient, and then place it in the ViSi Mobile Charger.

Never connect the ViSi Mobile Monitor directly to an AC power outlet. To recharge the battery, disconnect the Monitor from the patient, and then place it in the ViSi Mobile Charger.

Never connect the ViSi Power Pack directly to an AC power outlet. To recharge the battery, disconnect the Power Pack from the patient, and then place it in the ViSi Mobile Charger.

Do not touch the electrical contacts on the ViSi Power Pack or use the ViSi Power Pack without it first being inserted into the ViSi Power Pack Cradle. Doing so may result in electric shock from the battery.

When not in use, disconnect the ViSi Power Pack from the Monitor.

Do not modify the ViSi Power Pack in any way.

If the ViSi Power Pack beeper/buzzer sounds or the Red LED is permanently lit, the ViSi Power Pack should be disconnected from the patient immediately.

To prevent possible cross-contamination, properly clean and disinfect all reusable components between patients.

The ViSi Mobile Monitor should never be used to measure the NIBP of one patient while the Monitor is simultaneously connected to another patient.

Do not attempt to take NIBP measurements with the ViSi Mobile Monitor while the patient is undergoing cardio-pulmonary bypass.

Do not attempt to take NIBP measurements with the ViSi Mobile Monitor while the patient is being treated with an intra-aortic balloon pump or left ventricular assist device.

Periodically observe the patient’s arm for signs of impaired circulation, which may be a result of NIBP measurements made too frequently. Loosen or remove the ViSi Mobile Disposable Cuff if signs and/or symptoms of prolonged impaired circulation are evident.

Never place the ViSi Mobile Monitor, the ViSi Mobile Cuff Module, or the ViSi Power Pack into the ViSi Mobile Charger while connected to a patient.

Do not clean the ViSi Mobile Monitor, Cuff Module, Chest Sensor, Thumb Sensor, or ViSi Power Pack with detergents while worn by the patient.

Do not place the ViSi Mobile Monitoring System or ViSi Power Pack on or over an implanted programmable medical device.

When the “Monitor Too Hot” alarm is in progress, the ViSi Mobile Monitor and Chest Sensor should be removed from the patient immediately. Leaving them on the patient for an extended period of time may lead to a skin burn.

When the “Cuff Battery Temp” alarm is in progress, the ViSi Mobile Cuff Module should be removed from the patient immediately. Leaving it on the patient for an extended period of time may lead to a skin burn.

Disposable Components

All disposable components of the ViSi Mobile Monitoring System are for single patient use only. To avoid possible cross contamination, do not reuse any disposable items on a patient other than the original patient. Dispose of the components and any packaging material after use per your facility’s policy or national requirements.

Warnings

Patient Monitoring

Do not connect more than one ViSi Mobile Monitor to a patient.

Do not connect more than one patient to a single ViSi Mobile Monitor.

The ViSi Mobile Monitor, Thumb Sensor, Cuff Module, and the Chest Sensor must all be connected to the same arm for the System to function correctly.

The Wrist Strap should securely hold the ViSi Mobile Wrist Cradle in place without impairing circulation. Immediately loosen the Wrist Strap if the patient complains of pain, tingling, or numbness in the affected hand or wrist.

Only use the ViSi Mobile Chest Sensor provided by Sotera Wireless, Inc. for the ViSi Mobile Monitoring System. The Chest Sensor is designed to provide defibrillation protection as indicated in the Specifications section of this manual. ViSi Mobile is designed to be compatible with the use of external defibrillators.

Only use the ViSi Mobile Thumb Sensor provided by Sotera Wireless, Inc. with the ViSi Mobile Monitoring System. Using non-approved Thumb Sensors may result in inaccurate SpO_2 readings or damaged equipment.

The ViSi Mobile Thumb Sensor is intended for use on the patient's thumb, index and middle finger for SpO_2 measurements; however, cNIBP can only be measured while on the patient's thumb.

Warnings

Inspect the patient's skin at the sensor site per your facility's protocol. If the skin surface has been compromised, reposition the ViSi Mobile Thumb Sensor or move the Thumb Sensor to the patient's other thumb. If the thumb sensor is moved to the other thumb, move the other sensors as well.

Ensure that the ViSi Mobile Thumb Sensor is securely fastened. A Thumb Sensor that is wrapped too tightly or too loosely can adversely affect SpO_2 measurement.

The Thumb Wrap should securely hold the ViSi Mobile Thumb Sensor in place without impairing circulation. Immediately loosen the Thumb Wrap if the patient complains of pain, tingling, or numbness in the affected thumb.

To prevent settings from being inadvertently changed, lock the ViSi Mobile Monitor screen (if enabled) as soon as tasks are completed.

Keep all pacemaker patients under close or constant observation. Pacemaker signals can differ among pacemakers, ICDs, or CRT devices. The Association for the Advancement of Medical Instrumentation (AAMI) cautions: "In some devices, rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms".

ViSi cNIBP has not been evaluated in patients with pacemakers that pace the ventricle. ViSi's NIBP may be used instead.

After monitoring has been stopped on the ViSi Mobile Monitor, and the patient has been removed from the Remote Viewer, this action cannot be undone. Once removed, the patient's monitoring session data will no longer be available on the Remote Viewer.

A qualified clinician must always be in direct view of the ViSi Mobile Remote Viewer. If the Remote Viewer display is blank, contact your biomedical engineer immediately for service.

If a ViSi Mobile Monitor or the ViSi Mobile Remote Viewer display screen is scratched or damaged, immediately send it for servicing. A scratched or damaged screen can interfere with patient monitoring.

Always consult Sotera Wireless, Inc. before performing any changes to the ViSi Mobile Appliance. Server changes can result in communication failure between components of the ViSi Mobile Monitoring System. If system communication stops, monitor patients at the ViSi Mobile Monitors.

Perform a risk assessment and verification before implementing a change or modification to the IT infrastructure. Changes to IT network configurations can compromise continuous vital signs monitoring and alarm delivery.***Vital Signs***

If a vital signs measurement is questionable, retake the measurement. If the result is still questionable, use a different method of measurement.

ViSi Mobile blood pressure measurements (NIBP and cNIBP) have not been clinically evaluated in the presence of atrial or ventricular arrhythmias. Use alternative BP methods if these arrhythmias are present.

Chest Sensor: ECG, Respiration, Temperature (Skin)

Use all of the same type of high quality ECG electrodes on the patient. Mixing ECG electrode types can adversely affect ECG monitoring.

Avoid placing the ViSi Mobile Cable Securements and ECG electrodes over areas of abrasions, irritation, or other sensitive areas. If possible, remove, reposition, and replace ECG electrodes and Cable Securements if the patient complains of pain/itching at the sites.

The ViSi Mobile Monitor does not provide automated arrhythmia analysis. As a result, certain arrhythmias may cause the Monitor to display variable heart rates. If frequent arrhythmias are suspected, their presence should be confirmed by visual observation of the ECG waveform or another method, such as a 12-lead ECG.

The ViSi Mobile Monitor does not provide ST segment analysis. Therefore, if a change in the ST segment of the ECG waveform is suspected, it should be confirmed by another method, such as a 12-lead ECG.

Pacemaker signals can differ among pacemakers, ICDs, or CRT devices. The Association for the Advancement of Medical Instrumentation (AAMI) cautions: “In some devices, rate meters may continue to count the pacemaker rate during occurrences of cardiac arrest or some arrhythmias. Do not rely entirely upon rate meter alarms”. All pacemaker patients should be kept under close or constant observation.

External pacemakers or other external electrical stimulators may cause the ViSi Mobile Monitor to produce erroneous results.

RESP (chest wall motion) can continue in the absence of ventilation (obstructed airway). Do not rely on the RESP alone to determine adequacy of ventilation. Other vital signs, such as HR and SpO_2, should be assessed as well.

TEMP monitoring with the ViSi Mobile Monitoring System is intended for trending purposes only and is not intended to replace core temperature monitoring. Before making clinical decisions based on the skin temperature measurement, verify the measurement using another clinically acceptable method of core temperature measurement.

Warnings

Impedance pneumography for the determination of respiration (RESP) is not recommended for use in the presence of mechanically induced, high frequency ventilation.

Cuff Module / NIBP

ViSi Mobile Disposable Cuffs are for single patient use only. To avoid possible cross contamination, do not reuse a Cuff on a patient other than the original patient.

The ViSi Mobile Disposable Cuff should be snug enough to support the Cuff Module while not impairing circulation when deflated.

Avoid applying the ViSi Mobile Disposable Cuff over a wound as this can cause further injury.

Avoid applying the ViSi Mobile Disposable Cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present because of temporary interference to blood flow which could result in injury to the patient.

Take care in the application of the ViSi Mobile Disposable Cuff when applying the Cuff to an arm on the same side of a mastectomy. Recommend using the ViSi Mobile Monitoring System on the opposite arm.

ViSi Mobile NIBP measurements (1-time measurements or continuous measurements) have not been clinically evaluated in the presence of atrial or ventricular arrhythmias. Use alternative BP methods if these arrhythmias are present.

Inflate the ViSi Mobile Disposable Cuff only after proper application to the patient's limb.

If you are uncertain of the reliability of an NIBP measurement, repeat the measurement. If the reading is still suspect, use another method to measure the blood pressure.

SpO_2

Oxygen saturation measurements using SpO_2 are dependent on proper sensor placement, exposure to ambient light conditions, and general patient conditions. Before making clinical decisions based on SpO_2 measurements, verify the measurement using another clinically acceptable method, such as arterial blood gas analysis.

High ambient light conditions, including direct sunlight, may interfere with the performance of the ViSi Mobile Thumb Sensor.

Warnings

Low perfusion, electrosurgical devices, dysfunctional hemogolobin, the presence of certain dyes and inappropriate positioning of the ViSi Mobile Thumb Sensor may result in erroneous measurements.

Alarms / Alerts

When alarms are paused, there is no notification of a potentially clinically significant change in the patient's vital signs. Observe the patient by other means when alarms are paused.

When alarms are turned OFF, there is no notification of a potentially clinically significant change in the patient's vital signs. Observe the patient by other means when alarm limits are set to OFF.

Once Auto Set is selected (on the ViSi Mobile Monitor), review the newly calculated alarm limits carefully before deciding to confirm or cancel the new alarm limits. Once new alarm limits are confirmed on the ViSi Mobile Monitor, they cannot be changed back to the original pre-set limits from the ViSi Mobile Monitor. Use the ViSi Mobile Remote Viewing Device to change the alarm limits back to the original pre-set limits.

When the ViSi Mobile Monitor is not connected or loses wireless connection to the ViSi Mobile Appliance, the ViSi Mobile Remote Viewer does not receive patient alarms or alerts from the ViSi Mobile Monitor.

When the last source of monitoring is lost due to equipment (such as thumb sensor off, ECG leads off, all sensors disconnected) the visual annunciation of the alert will not have an audible component.

Line isolation monitor transients (artifacts) may resemble actual cardiac waveforms and inhibit heart rate alarms. Ensure correct electrode placement and cable arrangement to minimize line isolation monitor transients.

To avoid possible hearing damage, do not place your ear too close to the ViSi Mobile Monitor when it is alarming audibly.

When the ViSi Mobile Monitor alarms or alerts, check the patient first to confirm that there is no immediate danger to the patient.

When testing the speaker at the ViSi Mobile Remote Viewer, you are testing how the alarm and alert tones will sound at the Remote Viewer during typical operation. If the volume is inadequate, clinicians could miss alarms and alerts. During testing, if the tone does not sound or it is not loud enough, adjust the speaker volume.If the sound is still not loud enough, immediately contact a biomedical engineer.

The ViSi Power Pack Alarms/Alerts DO NOT audibly annunciate on the ViSi Mobile Monitor or the Remove Viewing Device.

Warnings

If the ViSi Mobile Monitor displays a “Battery Pack Fault” , “Electric Shock”, or “Monitor Too Hot” message, disconnect the Power Pack immediately.

User Maintenance

To avoid contaminating or infecting personnel, the environment or other equipment, make sure to disinfect and decontaminate the ViSi Mobile Monitoring System, Thumb Sensor and disposables appropriately before disposing of them in accordance with your country's laws for equipment containing electrical and electronic parts.***Wireless Communications***

When the ViSi Mobile Monitor is not configured to connect to the facility's network or loses wireless connection to the ViSi Mobile Appliance, the ViSi Mobile Remote Viewer does not receive patient alarms or alerts from the ViSi Mobile Monitor.

All wireless devices are susceptible to radio frequency interference that can disrupt connectivity. If excessive ViSi Mobile Monitoring System disconnections are observed, notify your biomedical engineer. Excessive disconnections can cause interrupted patient monitoring; disconnections must be investigated and corrected.

Other RF radiating devices (such as high powered RFID readers and Bluetooth devices) that are in close proximity with the ViSi Mobile Monitor may interfere with the Monitor's wireless communications. During such interference, the Monitor continues to monitor and will alarm locally. If wireless communication is affected when using the Monitor in close proximity with another RF radiating device, move the other device away from the Monitor or discontinue use of the other device.If you have any concerns regarding a cyber security breach or vulnerability, contact Sotera Wireless, Inc. or an authorized Sotera Wireless, Inc. representative in your area.

Off-The-Shelf (OTS) Software

The use of any software other than those specified in this manual will violate the safety, effectiveness and design controls of this medical device and such use may result in an increased risk to users and patients.

2.3 Cautions ⚠

Intended Use

Federal (U.S.A.) law restricts the ViSi Mobile Monitoring System and Power Pack to the sale, distribution, or use by, or on the order of a licensed medical practitioner.

The effectiveness of the ViSi Mobile Monitoring System's blood pressure monitoring has not been established in pregnant, including pre-eclamptic, patients.

General

Placing the ViSi Mobile Monitor into the Charger when the "All Sensors Disconnected" alert is displayed will result in the patient's monitoring session being stopped. It is recommended that you follow the correct stop/pause monitoring flows.

When monitoring has been paused, monitoring may only be resumed using the same ViSi Mobile Monitor. If you place the ViSi Mobile Monitor into the Charger with other Monitors, label the Monitor so that is can be identified when monitoring is to be resumed.

Moving the ViSi Mobile Monitor out of the network range will break the radio link, immediately stopping communication of patient vital signs data to the ViSi Mobile Remote Viewer.

When the wireless connector symbol is yellow, the ViSi Mobile Monitor is unable to connect to the ViSi Mobile Remote Viewer (via the ViSi Mobile Appliance).

Only the ViSi Power Pack should be placed into the accompanying cradle.

To avoid damage, the ViSi Power Pack should only be connected to the ViSi Mobile® Monitor.

Monitoring

The accuracy of cNIBP is dependent on the initial cuff calibration. Use good clinical practice to confirm cNIBP accuracy before initiating or treating a patient.

The accuracy of the cNIBP measurement cannot be relied upon in patients with a BMI greater than 35.

Due to cNIBP signal averaging, there is a time delay of up to 120 seconds between the instantaneous blood pressure reading and the displayed reading.

The ViSi Mobile Monitoring System accuracy claim (mean error of ≤ ±5 mmHg and a std. dev. of ≤ 8 mmHg) is not met when the subject is in a semi-Fowlers position (inclined more than 30 degrees from horizontal).

2-way radios may cause waveform distortion when placed within 1 foot of the ViSi Mobile Monitor.

Some brands of television may cause temporary waveform distortion and data loss when placed within 6 feet of the ViSi Mobile Monitor.

Safety

The ViSi Mobile Monitoring System or Power Pack have not been tested in the presence of flammable anesthetics or other flammable agents in combination with air, nitrous oxide, or oxygen-enriched environments.

Do not use a ViSi Mobile Monitor, its components, Power Pack or other accessories that appear damaged. Inspect all reusable components for damage before each use.

Do not attempt to connect any patient worn component, ViSi Chest Sensor or ViSi Mobile Cuff Module, or ViSi Power Pack to an electrical outlet of any kind.

A component that has been dropped or severely abused should be checked by qualified service personnel before use on a patient.

The ViSi Mobile Monitoring System or Power Pack are not intended for home use.

Do not use the ViSi Mobile Monitoring System or Power Pack to monitor a patient in a wet environment, such as a shower.

Explosion Hazard. Do not use in the presence of a flammable anesthetic mixture with air, or with oxygen or nitrous oxide.

Use care when using automatic cuff inflation for prolonged periods on unconscious or semi-conscious patients since the patient may not be able to alert the clinician to any pain he/she may be experiencing. Pressing the “Stop NIBP” button interrupts the NIBP measurement and deflates the cuff.

Consult your Biomed department or vendors for assistance in identifying EMC compliance status of other medical devices when using the ViSi Mobile Monitoring System or Power Pack.

Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.

Changes in posture and arm height can affect ViSi cNIBP accuracy. If the cNIBP measurement is questionable, retake the measurement. Ideally recalibrate in the same position as the initial calibration.

Cautions

The accuracy of the cNIBP measurement cannot be relied upon in patients with a BMI greater than 35.

Due to cNIBP signal averaging, there is a time delay between the instantaneous blood pressure reading and the displayed reading.

You should manually recalibrate cNIBP after the administration of an IV vasoactive drug or a new oral vasoactive drug. The Calibrate cNIBP alert will not be displayed.

If using the ViSi Mobile Monitor with any other monitor on the same patient, check that each monitor does not interfere with the operation of the other. If interference is detected, remove one or more of the sensors until there is no longer any interference.

Service / Maintenance

If the ViSi Mobile Monitor detects an unrecoverable problem, an error message containing the error number is displayed. Remove the Monitor from use and report the error to Sotera Wireless, Inc Customer Service.

When the ViSi Mobile Monitor is in the Charger and a charging alert occurs, remove the Monitor from service.

General maintenance of the ViSi Mobile Monitoring System should be conducted at the hospital defined intervals.

The ViSi Mobile Monitoring System components, including the ViSi Power Pack should only be serviced by Sotera Wireless, Inc. technicians or authorized service providers.

Equipment / Components

If the ViSi Mobile Monitor is to be stored for an extended period of time, it is recommended the Monitor be stored with the Shipping Plug inserted to reduce the battery discharge. The ViSi Mobile Monitor must always have the Shipping Plug inserted when shipped by a common carrier to comply with Federal Regulations regarding electromagnetic emissions.

When inserting the ViSi Mobile Monitor into the Wrist Cradle, ensure proper alignment: flat end to flat end, with the round end pointing towards the wrist.

Selection of the correct ViSi Mobile Disposable Cuff size is necessary to ensure accurate NIBP measurements. A Cuff that is too small can result in a falsely high NIBP measurement. A Cuff that is too large can result in a falsely low NIBP measurement.

Avoid touching the ViSi Mobile Disposable Cuff during cuff inflation as it may disrupt the measurement.

Cautions

To avoid damage from dropping the ViSi Mobile Monitor, ensure that the Wrist Strap is snugly wrapped around the wrist.

To avoid damage from dropping the ViSi Mobile Monitor while it is connected to the patient, secure the ViSi Mobile Monitor by plugging in the thumb sensor or locking key.

The performance of the automated sphygmomanometer may be affected by extremes of temperature, humidity and altitude.

The ViSi Mobile Monitoring System may not perform to specification if stored or shipped outside the specified temperature range.

The ViSi Mobile Monitor may be temporarily interrupted by UHF RFID Systems (860-960MHz).

When using a ViSi Power Pack equipped with a mount, ensure the clamp is properly secured to the bedside or IV Pole to avoid damage from being dropped.

Avoid from putting the ViSi Power Pack directly below an IV bag.

Avoid putting anything other than the ViSi Power Pack into the cradle.

Route the ViSi Power Pack cable away from other medical equipment in its vicinity.

Cleaning / Disinfecting

Do not clean the ViSi Mobile Monitor, the Cuff Module, or the Power Pack while it is plugged into the ViSi Mobile Charger.

Do not apply liquid to the ViSi Mobile Cuff Module or the Power Pack. To clean, use a damp cloth.

Ensure the sensor connector contacts are thoroughly dried to prevent possible malfunction.

Thumb sensors which are saturated with liquid should be allowed to air dry thoroughly before re-use.

Do not use bleach, abrasive cleaning agents or organic solvents on any of the ViSi Mobile Monitoring System components.

Use only recommended cleaning/disinfecting agents to prevent damage to the device and components. See page 107

Do not autoclave the ViSi Mobile Monitor, its components, or accessories.

Do not use excessive amounts of liquid when cleaning the ViSi Mobile Chest Sensor or the ViSi Mobile Thumb Sensor.

Cautions

After patient use, the disposables from the ViSi Disposable Kit may contain bio-hazard materials. Handle and dispose of these items according to your facility's policies.

When the ViSi Mobile Cuff Module is connected to the other ViSi Mobile Components, the entire system has an ingress protection rating of IPX0.

2.4 Notes

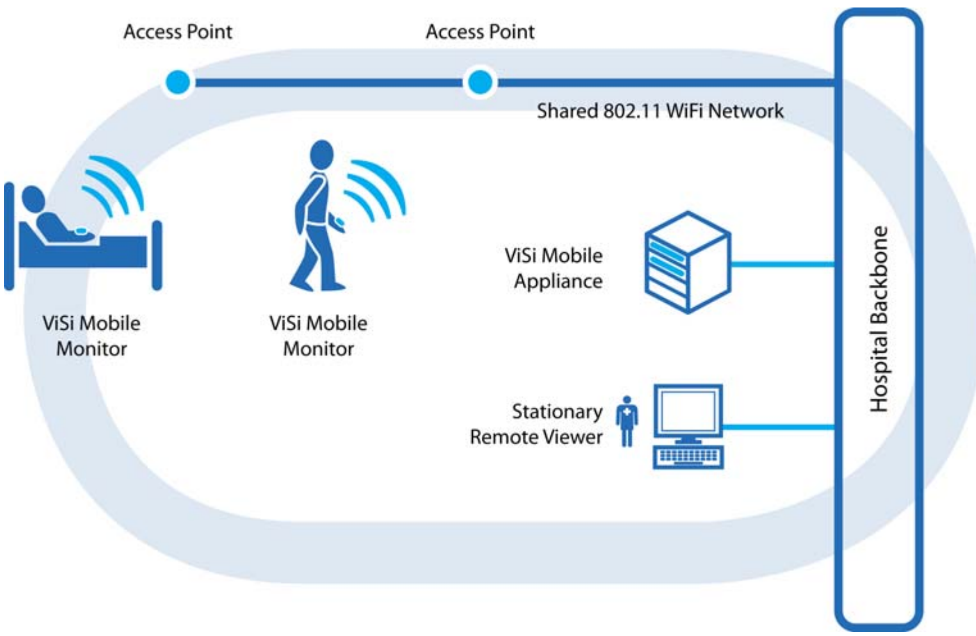
Note: Figures in this manual are provided for reference purposes only. Screens may differ based on the monitoring device configuration, licenses available, parameters selected and patient configuration of the ViSi Mobile Monitoring System.

Note: All ViSi Mobile Monitoring System alarms and alerts annunciate with icons and colors that comply with IEC 60601-1-8.

Notes

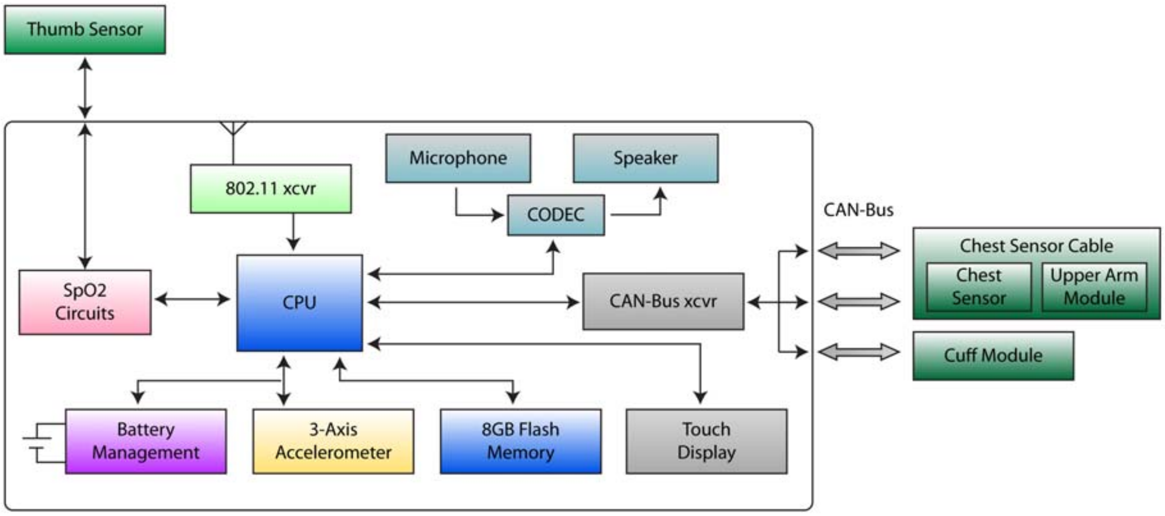
3. Theory of Operation

3.1 Introduction



ViSi Mobile Monitoring System

The ViSi Mobile Monitoring System enables clinicians to remotely monitor patients who are connected to ViSi Mobile Monitors. The System includes ViSi Mobile Monitors, a ViSi Mobile Appliance and a ViSi Mobile Remote Viewer. Information flows wirelessly and bi-directional between components.



ViSi Mobile Patient-Worn Monitor

The ViSi Mobile Patient-Worn Monitor continuously measures ECG/Heart Rate, Respiration Rate, NIBP, Skin Temperature, and SpO_2. The ViSi Mobile Monitor uses IEEE standards-based wireless communications to talk to the ViSi Mobile Appliance.

The main sub-components of the ViSi Mobile Patient-Worn Monitor are the ViSi Mobile Monitor, Chest Sensor Cable, Cuff Module and Thumb Sensor. These sub-components are connected to each other by a digital bus. The system is designed to strengthen the afferent limb of rapid response systems.

Each sub-component has specialized components for directly converting analog physiologic signals to the digital domain. Digitization of biological signals close to the sensors eliminates analog signal traversing cables found in traditional monitors that can cause artifact nuisance alarms. The on-body consolidation of all routine vital signs also reduces or eliminates the "spaghetti factor" found in current multi-parameter beside monitors that impede patient comfort and mobility.

The Chest Sensor, Upper Arm Module and Mobile Monitor each contain a three-axis accelerometer.

3.2 ViSi Mobile Monitor

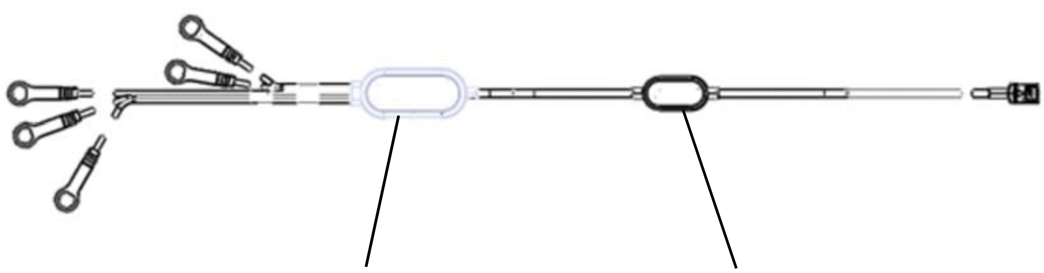
The ViSi Mobile Monitor serves as the hub of the patient-worn digital network. In this case, the Mobile Monitor supports the capture, storage, display, and alarming of all components. Measured vital signs with access to waveforms can also be displayed on a screen for clinician viewing.

Within the ViSi Mobile Monitor, a connector at the distal end facing the hand provides connection to a ViSi Mobile Thumb Sensor for pulse oximetry measurements or ViSi Mobile Mode Plugs for biomedical service and shipping. Three digital bus connectors on the opposite end provide digital connection to the ViSi Mobile Chest Sensor Cable (measuring ECG and posture), ViSi Mobile Cuff Module (measuring non-invasive blood pressure, NIBP), and future parameters. A speaker is incorporated to provide alarm annunciation.

The ViSi Mobile Monitor also provides wireless connectivity. The Wi-Fi 802.11b/g/n Monitor supports bidirectional communications to a dedicated ViSi Mobile Appliance located in the IT datacenter. TCP/IP protocols are used for all data, and the maximum data rate generated by the device when all parameters and waveforms are active is less than 20 KBps. In all such devices, security is an important design consideration. In this case, data security is ensured with Wi-Fi Protected Access 2 – Pre-Shared Key (WPA2-PSK) encryption.

The ViSi Mobile Monitor allows for submersion for cleaning and disinfection between patient uses.

3.3 ViSi Mobile Chest Sensor Cable



The Chest Sensor Cable (for either three- or five-lead ECG monitoring) is attached to the patient's upper torso near the midline. The back of the Chest Sensor incorporates a skin surface temperature sensor. Although skin surface temperature will differ from core body temperature, upward trends may indicate a rising fever.

Independent ECG channels are sampled at 500 Hz and include pacemaker detection, lead(s) off, and impedance respiration. A microprocessor detects beats and calculates heart rate (HR). Resulting waveforms, HR values and status (such as leads-off) are communicated to the ViSi Mobile Monitor via the digital bus.

The Upper Arm Module is used to correct for hydrostatic pressure used in the determination of continuous non-invasive blood pressure. It also serves as a mechanical anchor to the cable from the ViSi Mobile Monitor to the Chest Sensor Module.

The accelerometers within the Chest Sensor and the Upper Arm Module provide three axis posture, changes in posture and measures of motion. Motion is used to suspend respiration calculations in presence of motion artifact to reduce false alarms.

3.4 ViSi Mobile Cuff Module (NIBP)

The NIBP function is contained within the ViSi Mobile Cuff Module that connects directly to a ViSi Mobile Disposable Cuff (supplied by Sotera Wireless). The module includes an integrated battery, dual microprocessors, and a digital bus connector.

Blood pressure measurements are determined during the cuff inflation cycle rather than the deflation cycle. Measurements taken during inflation avoids over-inflation and lowers overall power consumption and measurement time.

Measurements are passed to the ViSi Mobile Monitor for display; there is no display on the ViSi Mobile Cuff Module.

3.5 ViSi Mobile Thumb Sensor

The Thumb Wrap holds the Thumb Sensor and secures it to the base of the patient's thumb. The Thumb Sensor is connected to the ViSi Mobile Monitor at the rounded end of the Monitor.

3.6 ViSi Mobile Remote Viewer / Appliance

Data originating from the ViSi Mobile Patient-Worn Monitor are similar to requirements for voice over Internet Protocol (VOIP) telephony applications. In the ViSi Mobile Monitoring System, data is captured in the ViSi Mobile Appliance which acts as an enterprise hub. The Appliance is dedicated hardware installed in the IT datacenter for secure network connectivity and emergency power backup.

A secure remote access (similar to a VPN) connection allows remote service support and software updates.

Clinical data from up to 32 patients can be displayed on a single ViSi Mobile Remote Viewer. Patients are manually admitted to the ViSi Mobile Monitoring System.

3.7 Alarm Management

Alarms originate from the ViSi Mobile Monitor. A bidirectional interface (via the ViSi Mobile Appliance) ensures remote alarm annunciation on the ViSi Remote Viewer(s). Remote Viewer(s) display both waveforms and alarm values as well provide an interface for a clinician to silence an alarm. Visual icons and audible annunciation conform to the IEC 60601-1-8 standard.

Threshold alarms are set at factory default values but may be reconfigured at installation. Audio alarm annunciation can be delayed based on alarm type, severity, and preconfigured time. Audio alarm delays allow filtering of short duration nuisance alarms.

Alarm annunciation delays have been shown to reduce nuisance alarms by adding a simple rule of persistence to the vital signs value. When a non-life threatening alarm is annunciated, the audio component of the annunciation is deferred to the ViSi Remoter Viewer(s) for a short period of time. This reduces the disturbances to the patient.

Activating autoset (from the ViSi Mobile Monitor) changes all alarm parameters that are currently in alarm to new set points depending on the patient's current condition. The degree of change depends on the current patient value compared to default alarm limits. Patient alarm settings may also be changed from the ViSi Remote Viewer, which is in line with other types of multi-parameter monitoring systems.

3.8 ViSi Mobile Charger

The ViSi Mobile Charger is used to charge both ViSi Mobile Monitors and Cuff Modules, providing two or eight charging docks for simultaneously charging multiple units. The Charger consists of a desktop/wall mount charger, power supply and power cable.

The LED on the Charger is used to indicate the charging status of devices that are currently inserted:

LED Color	Charging Status
Steady Green	Everything is functional: • No devices in the Charger. • All devices are charging normally or are fully charged.
Flashing Green / Yellow	At least one device in the Charger has not properly registered with the Charger, but charging continues on all devices. Devices with fully drained batteries cannot register with the Charger until after a charge cycle starts and will cause this condition until they reach a minimum charge level. Removing and reinserting an unregistered device can give it another chance to register in the Charger. If this condition is repeatedly observed on devices that are not fully drained, contact Sotera Wireless or an authorized Sotera Wireless representative in your area.
Steady Yellow	At least one device in the Charger is not being charged due to a fault with the device. All other devices are charging. Contact Sotera Wireless or an authorized Sotera Wireless representative in your area.
Steady Red	Charger fault. No devices are charging, the Charger has shutdown. Contact Sotera Wireless or an authorized Sotera Wireless representative in your area.

- *Notes* -

4. Specifications

4.1 Introduction

This section provides specifications regarding measurement ranges, accuracy levels and environmental operating conditions for the ViSi Mobile Monitoring System.

⚠ Do not use the ViSi Mobile Monitoring System in neonatal or pediatric patients (under the age of 18 years) since the System has not been evaluated for these patient groups.Do not use the ViSi Mobile Monitor as a primary hypoxia diagnostic tool.

4.2 Vital Sign Measurements

4.2.1 Heart Rate

Heart Rate	
Display Range	0 to 240 BPM
Accuracy Range	30 to 240 BPM
Accuracy	±3 BPM
Resolution	1 BPM
Pacemaker	• The monitor detects and rejects pacemaker impulses in accordance with ANSI/AAMI/IEC 60601-2-27:2011 - • Performs heart rate calculations on a patient with a pacemaker • Will not recognize a pacemaker impulse as a QRS • Displays pacer markers on ECG waveforms
Pacemaker Pulse Rejection Without Overshoot	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 201.12.1.101.13: Pulse Rejection Range: Amplitude from ±2 mV to ±700 mV Pulse Width from 0.1 ms to 2 ms Indicated Heart Rate: Ventricular Pacing: Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM Atrial / Ventricular Pacing: Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM **Note: At 30 BPM, asynchronous pacing may trigger occassional R-wave detection**

Heart Rate	
Pacemaker Pulse Rejection With Overshoot	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 201.12.1.101.13, Method A: Pulse Rejection Range: Amplitude from ±2 mV to ±700 mV Pulse Width from 0.1 ms to 2 ms **Note: Pulses with polarization overshoot > 4 ms may cause R-wave** Indicated Heart Rate: Ventricular Pacing: Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM Atrial / Ventricular Pacing: Case (a): 0 BPM Case (b): 60 BPM Case (c): 30 BPM **Note: At 30 BPM, asynchronous pacing may trigger occassional R-wave detection**
Defibrillation Response	• Defibrillator protected • Displays HR measurement < 30 seconds after a defibrillation event • Displays an ECG waveform < 10 seconds after a defibrillation event **Note: Defibrillation events may be implanted or external.** **Note: Defibrillation recovery is dependent upon using proper disposable electrodes. Use only Ag-AgCl disposable electrodes.**
T-Wave Rejection	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 201.12.1.101.17: • T-waves up to 1.65 mV in amplitude: • T-waves not detected, no change in indicated heart rate.
Heart Rate Averaging	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 201.7.9.2.9.101, b) 3): • 20 second moving average
Heart Rate Accuracy and Response to Irregular Rhythm	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 201.7.9.2.9.101, b) 4): • Waveform 3a: 80 BPM • Waveform 3b: 60 BPM • Waveform 3c: 60 BPM • Waveform 3d: 90 BPM
Change in Heart Rate	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 201.7.9.2.9.101, b) 5): • 80 BPM to 120 BPM: 15 seconds • 80 BPM to 40 BPM: 15 seconds
Time to Alarm for Cardiac Standstill	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 208.6.6.2.103: • < 15 seconds
Time to Alarm for Low Heart Rate	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 208.6.6.2.103: • < 15 seconds

Heart Rate	
Time to Alarm for High Heart Rate	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 208.6.6.2.103: • < 15 seconds
Time to Alarm for Tachycardia	Tested per ANSI/AAMI/IEC 60601-2-27:2011 , 201.7.9.2.9.101, b) 6): Figure 4a: • 12 seconds • Gain = 2.0x: <12 seconds • Gain = 0.5x: < 5 seconds Figure 4b: • Gain = 1.0x: < 10 seconds • Gain = 2.0x: <10 seconds • Gain = 0.5x: < 5.5seconds
Input Impedance	> 20 Mohms
Frequency Response	0.5 to 125Hz
Lead Off Detection Current	< 24 nA
Common Mode Rejection Ratio	> 85 dB

4.2.2 Respiration

Respiration	
Method	Impedance Pneumography
Display Range	0 to 50 BR/MIN
Accuracy Range	3 to 50 BR/MIN
Accuracy	± 3 BR/MIN or 10% of reading, whichever is greater
Resolution	1 BR/MIN
Respiration Drive	Voltage: 1.00 V P-P ±5% Frequency: 32.0 KHz ±2%

4.2.3 Pulse Oximetry (SpO_2, Functional Oxygen Saturation)

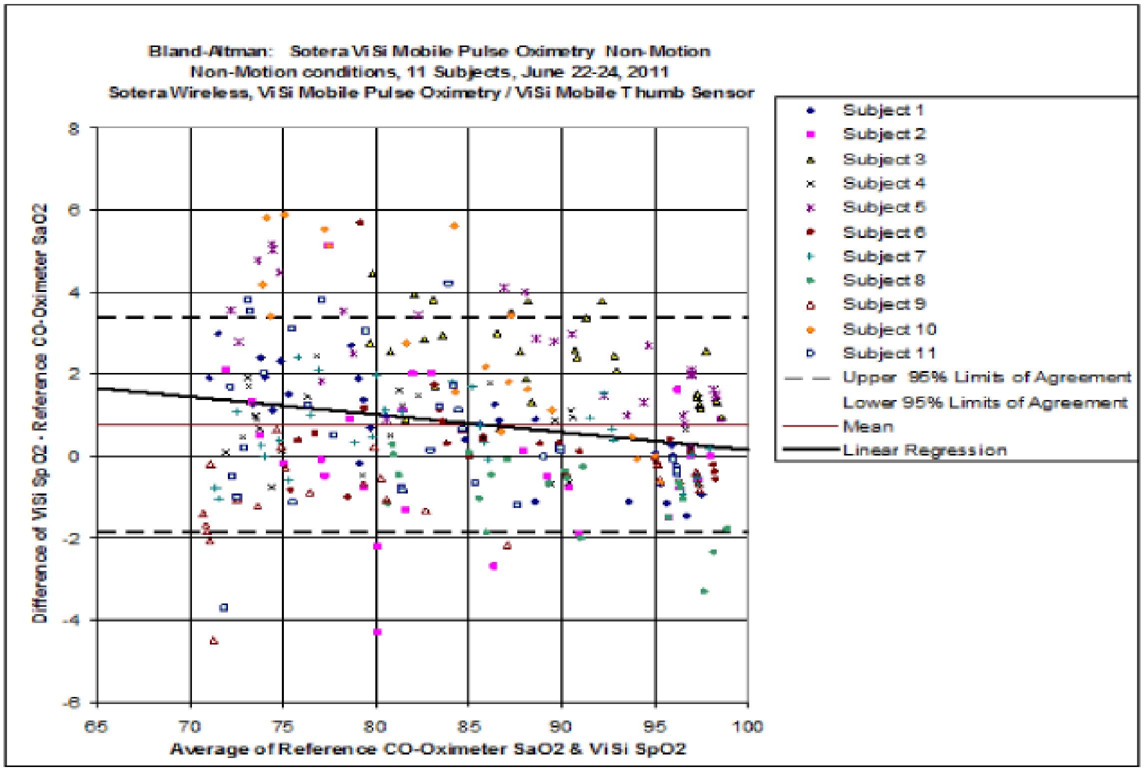
Pulse Oximetry (SpO_2, Functional Oxygen Saturation)		
Normative Reference	ISO 9919: 2005	
SpO_2	Display Range	49 to 100%
	Accuracy Range	70 to 100%
	Accuracy	≤ 2% from 70-100% (no motion)[a] Unspecified from 49-69%
	Resolution	1%
Pulse Rate	Display Range	0 to 240 BPM
	Accuracy Range	30 to 240 BPM
	Accuracy (No Motion)	± 3 BPM; < 50 BPM @ ≥ 0.6% Pulsatile Modulation ± 3 BPM; ≥ 50 BPM @ ≥ 0.4% Pulsatile Modulation
	Accuracy (RMS Error)	≤ 3 BPM
	Rate Resolution	1 BPM
Validation Study	Per ISO 9919. The ViSi SpO_2 is calibrated to display functional oxygen saturation and validated against human subjects arterial blood sample reference measured with CO-Oximeter (see Bland-Altman: ViSi Mobile Pulse Oximetry table). **Note: A functional tester cannot be used to assess the accuracy of a pulse oximeter probe or a pulse oximeter monitor.**	
Calculation Rate	Every pulse	
Display Refresh Rate	Every 3 seconds	
Averaging	12 beat average following initialization	
Alarm Range	Low - Fixed at 85%	
Alarm Delay	30 seconds (fixed)	
Waveform Display	• Amplitude is normalized • Sweep speed is scaled to 25mm/sec to match ECG	
Sensor Application Time	Sensor should be checked every 8 hours	
Optical Wavelengths / power	Red: 660nm / max 6.5mW (±15%) Infra-Red: 905nm / max 5.2mW (±15%)	
Interference	SpO_2 can be adversely affected by the presence of dyshemoglobin, ambient light (including photodynamic therapy); electromagnetic interference; electrosurgical units; dysfunctional hemoglobin; presence of certain dyes; inappropriate positioning of the pulse oximeter sensor.	
Toxicity	Thumb sensor uses white silicone which has no known toxicity effects.	
Measuring Maximum Temperature	Measuring the maximum temperature of the Thumb Sensor at the skin should be done with a calibrated temperature probe placed under the sensor when attached to the thumb.	

a. Bench testing indicates accuracy may be compromised at pulse rates below 50BPM at modulations less than 0.6% and extremely low pulse rates of 30BPM at modulations less than 0.8%.

The table below shows A_{rms} values measured using the ViSi Mobile Thumb Sensor (Model 92-10020) with the ViSi Mobile Monitoring System in a clinical study:

Validation Data (per ISO 9919)				
Age of Volunteers	18 - 45			
SpO_2 Accuracy (No Motion)				
SpO_2 Range	70-100%	90-100%	80-90%	70-80%
Accuracy (A_{rms}) - No Motion	1.9	1.2	1.9	2.4

Bland-Altman: ViSi Mobile Pulse Oximetry

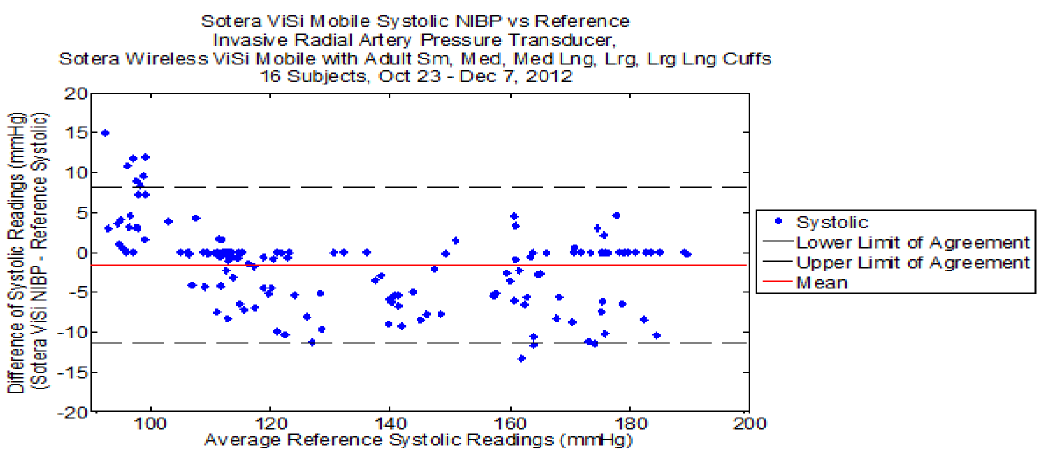


Note: **Test subjects were healthy, in an age range from 21 to 45 years (7 males and 4 females), with a wide range of skin pigmentation.**

4.2.4 Non-Invasive Blood Pressure (NIBP)

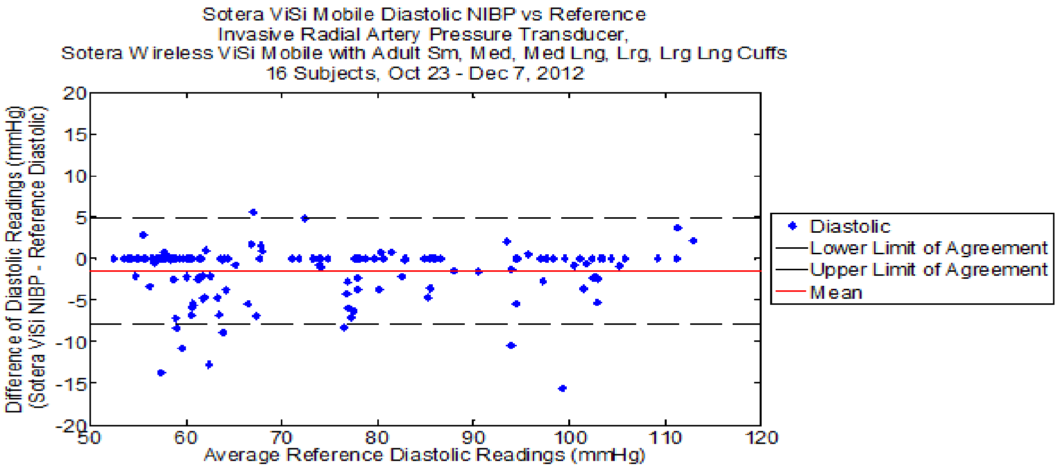
Non-Invasive Blood Pressure (NIBP)		
Normative Reference	ISO 81060-2: Non-invasive Sphygmomanometers - Part 2: Clinical validation of automated measurement type.	
Principle of Operation	Oscillometry	
Systolic	Range:	60 to 240 mmHg
	Accuracy:	Mean error of less than ± 5 mmHg and a std. dev. of ≤ 8 mmHg
	Resolution:	1 mmHg
Diastolic	Range:	40 to 160 mmHg
	Accuracy:	Mean error of less than ± 5 mmHg and a std. dev. of ≤ 8 mmHg
	Resolution:	1 mmHg
Mean Arterial Pressure	Range:	50 to 185 mmHg
	Accuracy:	Mean error of less than ±5 mmHg and a std. dev. of ≤ 8 mmHg
	Resolution:	1 mmHg
Pulse Rate	Accuracy (NIBP) <3 BPM	
Validation Study	Invasive blood pressure (radial artery) reference	
	Number of subjects: 16	
	Subject Age Range: 19-48	

Systolic Bland Altman Analysis (NIBP)



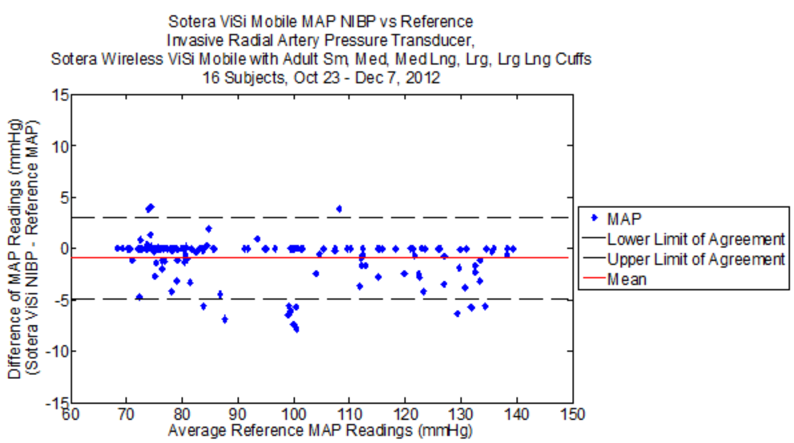
Sample Size:	152 data points
Mean:	-1.65 mmHg
Standard Deviation:	5.01 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	8.2 mmHg
Lower 95% Limits of Agreement (-1.96 SD):	-11.5 mmHg

Diastolic Bland Altman Analysis (NIBP)



Sample Size:	152 data points
Mean:	-1.49 mmHg
Standard Deviation:	3.22 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	4.8 mmHg
Lower 95% Limits of Agreement (-1.96 SD):	-7.8 mmHg

Mean Arterial Pressure Bland Altman Analysis (NIBP)



Sample Size:	152 data points
Mean:	-0.91 mmHg
Standard Deviation:	2.04 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	3.1 mmHg
Lower 95% Limits of Agreement (-1.96 SD):	-4.9 mmHg

4.2.5 Continuous Non-Invasive Blood Pressure (cNIBP)

Continuous Non-Invasive Blood Pressure (cNIBP)	
Normative Reference	ISO 81060-2: Non-invasive Sphygmomanometers - Part 2: Clinical validation of automated measurement type.
Principle of Operation	cNIBP is based on the relationship between blood pressure and the time it takes a pulse that originates from a cardiac contraction to arrive at a peripheral location.
Display Update	Continuous blood pressure is displayed based on averaging PAT calculations from the previous 60 seconds and updating the display every 3 seconds.
Systolic	Range: 60 to 240 mmHg Accuracy[a,b]: Mean error of ≤ ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution: 1 mmHg
Diastolic	Range: 40 to 160 mmHg Accuracy[a,b]: Mean error of ≤ ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution: 1 mmHg
Mean Arterial Pressure (MAP)	Range: 50 to 185 mmHg Accuracy[a,b]: Mean error of ≤ ± 5 mmHg and a std.dev. of ≤ 8 mmHg Resolution: 1 mmHg
Validation Study	Invasive blood pressure (radial artery) reference Number of subjects: 15 Subject age range: 19-48 years Arm circumference range tested: 21-38 cm

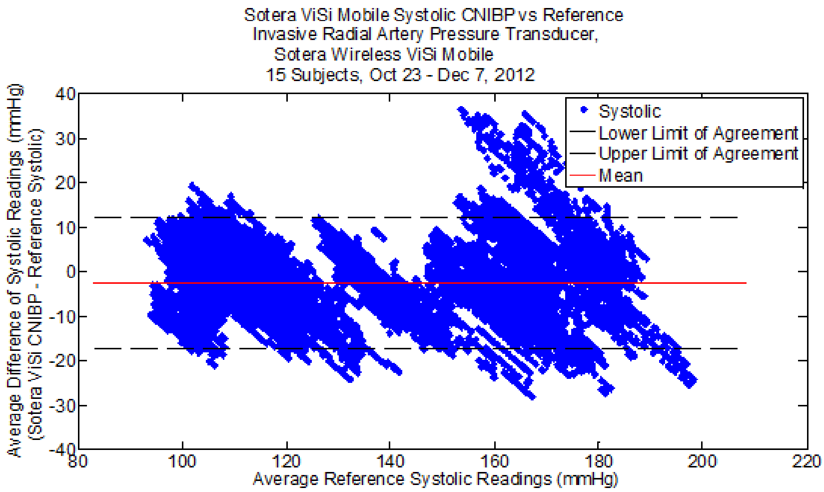
a. *ViSi Mobile Monitoring System accuracy claim is not met when the subject is inclined more than 30 degrees from horizontal.*
b. *The accuracy and precision of the cNIBP measurement met ISO 81060-2 requirements for the first 2.5 hours of testing.*

cNIBP Clinical Study Results
Sotera ViSi cNIBP vs. Reference Invasive Radial Artery Transducer (n=15 subjects)

Subject Position		**Supine**	**30º**	**60º**	**Overall**
Systolic	Bias	-1.61	-4.77	-7.36	-1.88
	Std. Dev.	5.69	7.87	9.97	6.17
Diastolic	Bias	-1.33	-3.97	-8.31	-1.65
	Std. Dev.	3.16	4.49	6.07	3.62
MAP	Bias	-0.33	-3.01	-7.23	-0.67
	Std. Dev.	3.36	5.37	6.67	3.86
Data Points		47,572	1,774	1,724	54,179

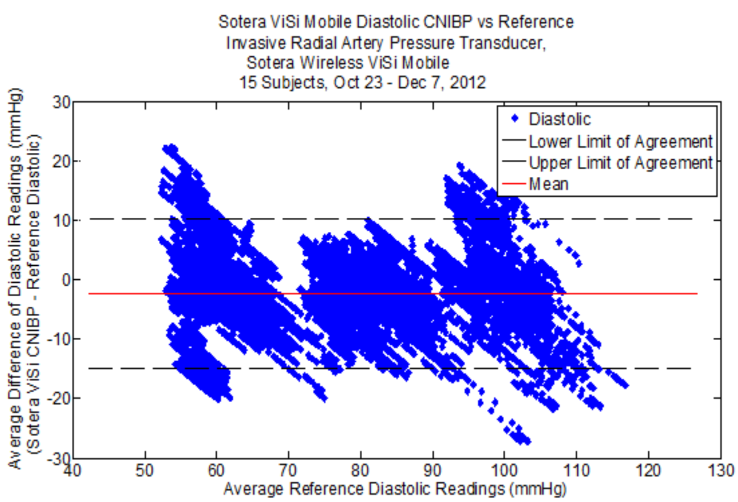
Changes in posture and arm height can affect ViSi cNIBP accuracy. If the cNIBP measurement is questionable, retake the measurement. Ideally recalibrate in the same position as the initial calibration.

Systolic Bland Altman Analysis (cNIBP)



Sample Size:	54,179 data points
Mean:	-1.88 mmHg
Standard Deviation:	6.17 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	10.2 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-14.0 mmHg

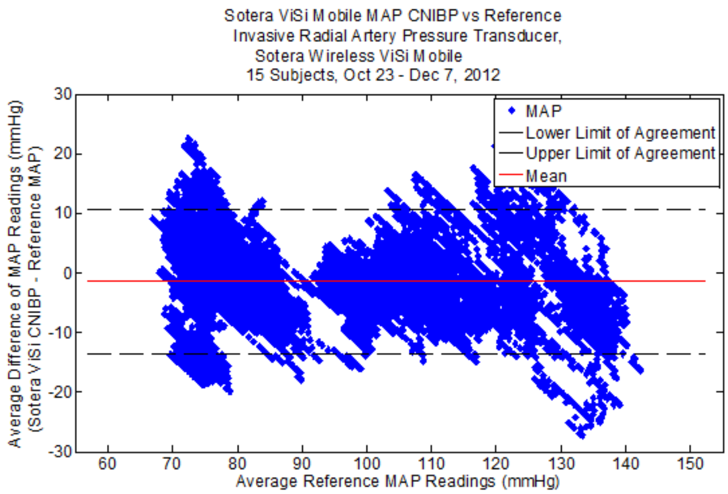
Diastolic Bland Altman Analysis (cNIBP)



Sample Size:	54,179 data points
Mean:	-1.65 mmHg

Standard Deviation:	3.62 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	5.4 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-8.7 mmHg

MAP Bland Altman Analysis



Sample Size:	54,179 data points
Mean:	-0.67 mmHg
Standard Deviation:	3.86 mmHg
Upper 95% Limits of Agreement (+1.96 SD):	6.9 mmHg
Upper 95% Limits of Agreement (-1.96 SD):	-8.2 mmHg

4.2.6 Skin Temperature

Temperature				
Scale	^oC		^oF	
Range / Accuracy (measurement at approximately 102 kPa / 768 mmHg)	Range	Accuracy	Range	Accuracy
	0^o - 19.9^o	$\pm 0.3^o$	32^o - 67.9^o	$\pm 0.5^o$
	20^o - 24.9^o	$\pm 0.3^o$	68^o - 76.9^o	$\pm 0.5^o$
	25^o - 35.9^o	$\pm 0.2^o$	77^o - 96.7^o	$\pm 0.3^o$
	36^o - 39.9^o	$\pm 0.1^o$	96.8^o - 103.9^o	$\pm 0.2^o$
	40^o - 41.9^o	$\pm 0.2^o$	104^o - 107.5^o	$\pm 0.3^o$
Resolution	$\pm 0.1^o$		$\pm 0.1^o$	
Transient Response	< 6 min (25^o - 37^o)		< 6 min (77^o - 98.6^o)	

Note: The above skin temperatures have not been evaluated for correlation to core temperatures.

4.3 Physical Components

4.3.1 ViSi Mobile Monitor

ViSi Mobile Monitor		
Physical Characteristics	Dimensions	2.59 cm H x 4.85 cm W x 9.35 cm L 1.02 in. H x 1.91 in. W x 3.68 in. L exclusive of connectors and Wrist Cradle
	Weight	110 g / 3.92 oz
Monitor	Display	OLED, 160 x 128 pixels, full color
	Audio	Alarm annunciation, QRS, self-test
	Waveforms	One waveform, user selectable Aspect Ratio: 0.4 Sec/mV Scaled equivalent to 25 mm/sec sweep speed Respiration waveform scaled equivalent to 6.25 mm/sec sweep speed
Battery	Operating Time	> 12 hours
	Fuel Charge Display	Battery Symbol Charge Level with Full Indication
	Charge Time	Less than 4 hours
	Battery Type	Li-Ion, 3.7 V., 2000 mAh, single cell
	Maximum Temperature	45°C / 113°F *Refer to IEC 60601-1:2005 (Section 11)*
Cleaning / Disinfecting	Liquid Ingress Rating	IPX7 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• ≤70% Isopropyl alcohol (IPA) • Detergent (Alconox)

Wireless Communications / Radio

Wireless Communications	
Frequency	2.412 - 2.462 GHz
Protocol	802.11 b/g/n
Modulation	DSSS, OFDM, DBPSK, DQPSK, CCK, 16-QAM and 64-QAM
Security	WPA2 / PSK, AES
Power Output (max)	802.11 b: 15.8 dBm (38.3 mW)
	802.11 g: 12.9 dBm (19.5 mW)
	802.11 n: 11.8 dBm (15.1 mW)
Data Throughput	< 30 KBps

Other RF radiating devices (such as high powered RFID readers and Bluetooth devices) that are in close proximity with the ViSi Mobile Monitor may interfere with the Monitor's wireless communications. During such interference, the Monitor continues to monitor and will alarm locally. If wireless communication is affected when using the Monitor in close proximity with another RF radiating device, move the other device away from the Monitor or discontinue use of the other device.If you have any concerns regarding a cyber security breach or vulnerability, contact Sotera Wireless, Inc. or an authorized Sotera Wireless, Inc. representative in your area.

Mode Plugs

Mode Plugs	
Shipping Plug	Turns device off completely
Locking Plug	Secures Monitor into Wrist Cradle
Bio Med Mode[a]	Enables configuration and test functions

a. The Bio Med Mode is only available to hospital Bio Meds.

4.3.2 ViSi Mobile Chest Sensor

ViSi Mobile Chest Sensor		
Mechanical	Complies with EC53	
Weight (5 lead-wire / 3 lead-wire)	72 g / 62 g (2.54 oz. / 2.19 oz.)	
Operating Temperature	0 - 40ºC / 32ºF - 104ºF *Refer to IEC 60601-1:2005 (Section 11)*	
Cleaning / Disinfecting	Liquid Ingress Rating	IPX7 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• ≤70% Isopropyl alcohol (IPA) • Detergent (Alconox)

4.3.3 ViSi Mobile Cuff Module

ViSi Mobile Cuff Module		
Physical Characteristics	Dimensions	3.10 cm H x 4.85 cm W x 12.19 cm L (1.22 in. H x 1.91 in. W x 4.80 in. L) exclusive of cable
	Weight	157 g (5.54 oz)
Battery	Operating Time	> 30 cuff inflations or 24 hrs, whichever occurs first
	Charge Display Status	Eight LEDs: Six levels of Green, Yellow, Red
	Charge Time	< 4 hours
	Battery Type	Battery Pack, Li-Ion, 2000 mAh
	Maximum Temperature	45°C / 113°F *Refer to IEC 60601-1:2005 (Section 11)*
Cuff Sizes Arm Circumference (cm)	Small	20 – 26
	Medium	25 – 34
	Medium+	25 – 34
	Large	32 – 43
	Large+	32 – 43
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0
	Solutions / Compounds	• ≤70% Isopropyl alcohol (IPA) • Detergent (Alconox)

When the ViSi Mobile Cuff Module is connected to the other ViSi Mobile Components, the entire system has an ingress protection rating of IPX0.

4.3.4 ViSi Mobile Thumb Sensor

ViSi Mobile Thumb Sensor		
Cleaning / Disinfecting	Liquid Ingress Rating	IPX7 During cleaning cycle only, not during monitoring
	Solutions / Compounds	• ≤70% Isopropyl alcohol (IPA) • Detergent (Alconox)

4.3.5 ViSi Mobile Charger - 8 Bay

ViSi Mobile Charger		
Physical Characteristics	Dimensions	7.7 cm x 46.3 cm x 5.9 cm (3.0 in x 18.2 in x 2.3 in)
	Weight	0.7 kg (1.5 lb)
AC Mains	AC Line Voltage	100-240 V, 50-60 Hz
	Power (all bays charging)	75 W
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0
	Solutions / Compounds	• ≤70% Isopropyl alcohol (IPA) • Detergent (Alconox)

4.3.6 ViSi Mobile Charger - 2 Bay

ViSi Mobile Charger		
Physical Characteristics	Dimensions	7.7 cm x 12.9 cm x 5.9 cm (3.0 in x 5.1 in x 2.3 in)
	Weight	0.25 kg (0.6 lb)
AC Mains	AC Line Voltage	100-240 V, 50-60 Hz
	Power (all bays charging)	30 W
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0
	Solutions / Compounds	• ≤70% Isopropyl alcohol (IPA) • Detergent (Alconox)

4.3.7 ViSi Mobile Power Pack (Optional Accessory)

ViSi Power Pack		
Physical Characteristics	Dimensions	3.13 cm H x 4.87 cm W x 12.19 cm L (1.23 in. H x 1.91 in. W x 4.80 in. L) Cable Length 3 to 5 ft.
	Weight	172 g (6.07 oz.)
Battery	Operating Time	minimum 24 hrs
	Charge Display Status	Eight LEDs: Six levels of Green, Yellow, Red
	Charge Time	< 6 hours
	Battery Type	Battery Pack, Li-Ion, 2000 mAh
	Maximum Temperature	50ºC / 122ºF *Refer to IEC 60601-1:2005 (Section 11 for equipment not intended to contact patient)*
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0
	Solutions / Compounds	• ≤70% Isopropyl alcohol (IPA) • Detergent (Alconox)

ViSi Power Pack Cradle

ViSi Power Pack Cradle		
Physical Characteristics	Dimensions	4.87 cm H x 9.5 cm W x 10.0 cm L (1.91 in H x 3.74 in W x 3.93 in L)
	Weight	Without clamp: 91.3 g (3.22 oz.)
		With clamp 0.53 kg (1.17 lb.)
Cleaning / Disinfecting	Liquid Ingress Rating	IPX0
	Solutions / Compounds	• ≤70% Isopropyl alcohol (IPA) • Detergent (Alconox)

4.3.8 ViSi Mobile Appliance

ViSi Mobile Appliance	
Server Configuration	Single 1u, redundant hardware and internal RAID 10, dedicated hardware.
Processor	Single Intel Xeon 5620 2.4 GHz (or equivalent CPU) 8 GB memory
Storage	Server contains at a minimum 4 x 500 GB 7200 RPM hard drives in RAID 10 array
Operating System	**Note: SUSE Linux Enterprise Server (Version 11, Patch Level 2)**
Network Requirements	Static IP address or DHCP reservation required Multicast configuration on network backbone devices
Dimensions (Single Appliance, may vary)	H: 43.0 cm x W: 43.4 cm x L: 62.7 cm (w/o ear, w/o bezel) H: 1.7 in x W: 17.1 in x L: 24.7 in
Weight (Single Appliance)	35.02 lb (15.9 kg) (Maximum configuration weight)
Power Requirements (Single Appliance)	100-240 VAC, 50-60 Hz, 7 A - 3.5 A w/ redundant power supply
Backup Power Requirement (Full System)	Customer supplied Uninterruptable Power Supply and Hospital Emergency Power recommended.

In the ViSi Mobile Monitoring System, data is captured in the ViSi Mobile Appliance, which acts as an enterprise hub. The Appliance is dedicated hardware installed in the IT datacenter for secure network connectivity and emergency power backup. For more information on the ViSi Mobile Appliance, see the *ViSi Mobile Monitoring System Technical Reference Manual.*

4.3.9 ViSi Mobile Remote Viewer

ViSi Mobile Remote Viewer (Desktop PC with Touchscreen Display)	
No. of Patients per Remote Viewer	Maximum 32
Display	23 in display / 1920 x 1080 resolution (screen is touch sensitive to issue commands alternative to mouse/keyboard)
Processor	Intel i5 2400 CPU 4 Core 3.10 GHz 4 GB Memory
Storage	One 500 GB 7200 RPM SATA
Operating Systems	Microsoft® Windows® 7 Professional (version 6.1) x64 Bit SP1
Network Requirements	Ethernet Connection, DHCP
Dimensions	H: 45.0 cm x W: 58.5 cm x D: 10.3 cm H: 17.7 in x W: 23.0 in x D: 4.1 in
Weight	26.7 lb (12.1 kg)
Power Requirements	AC/DC Adapter Input: 100-240 V ~3.5 A, 50-60 Hz Output to Viewer: 19.5 V / 11.8 A
Backup Power Requirement	Customer supplied Uninterruptable Power Supply and Hospital Emergency Power recommended.

Note: Sotera Wireless, Inc. recommends installation of Trend Micro anti-virus software on Windows platforms. Anti-virus software is not installed on the ViSi Mobile Monitor.

Note: For printing capability, Sotera Wireless, Inc. recommends connecting a printer directly to the ViSi Mobile Remote Viewer or to an in-network printer via an IP address. Sotera Wireless, Inc. does not support additional configurations.

4.3.10 Customer Network

Wireless Network	
Wireless Network Standard	IEEE 802.11b/g/n
Recommended Channels	1, 6, 11
Network Latency	< 150 ms
Wireless Network Security Support	WPA2-PSK
Minimum Receiver Sensitivity	-65 dBm (edge coverage)
Wireless access point cell overlap	15-20%
Signal-to-Noise Ratio	≥25 dB
Packet loss	≤6%
SSID	Dedicated or shared with other medical devices

Wired Network	
Appliance (Server)	Requires static IP Address
Network availability	>99.9%

4.4 Alarms / Alerts Annunciation

Note: An "Annunciation Delay" is the time that an alarm system deliberately delays the alarm annunciation (audibly and visually) to ensure clinical relevance of the detected alarming condition. Within the tables below, see column "Annunciation Delay" for the pre-defined periods of time.

4.4.1 Physiological Alarms (Alarms)

Visual Display

The following table outlines the visual display when alarms are in progress:

Severity	Indicator Attributes	Toggle / Flash Speed	Duty Cycle
High Priority	Red	1.5 Hz	50% ON
Life-Threatening Priority	Red / White	1.5 Hz	50% ON

Audio Tones

The following table outlines the audio tones when alarms are in progress:

Severity	Melody[a]	Volume [dB]	Frequency (f_o) [Hz]	Duration (t_d) [ms]	Spacing (t_s) [ms]	5th-6th [s]	Inter-Burst (t_b) [s]
Life Threatening	b5.b5.b5..b5.b5	78	987.767	100	50	0.35	2.5
High	b5.b5.b5..b5.b5	78	987.767	200	100	0.35	5

a. Melodies are defined as musical notes.

Alarm Limits and Delays (factory default settings).

Vital Sign	Lower Limit		Upper Limit		Annunciation Delay[a]
	Care Unit	Patient	Patient	Care Unit	(seconds)
Critical Low HR (BPM)	18	18	N/A	N/A	5
Heart Rate (BPM)	30	30	150	200	5
Pulse Rate (BPM)	30	30	150	200	30
BP Systolic (mmHg)	70	OFF	190	240	120
BP Diastolic (mmHg)	40	OFF	OFF	150	120
BP MAP (mmHg)	60	65	OFF	170	90
Respiration (BR/MIN)	4	4	35	40	120
SpO_2 (%)	85	85	N/A	N/A	60
Skin Temperature	N/A	N/A	N/A	N/A	N/A

a. When measuring blood pressure as a 1-time measurement or at automatic intervals, there will be no annunciation delay.

Battery Alarms

No Pulse Detected Alarms	Limit	Annunciation Delay
When Thumb Sensor is primary source	No Pulse	No delay
When Cuff Module is primary source	No Pulse	No delay

	Battery Alarms	Limit	Annunciation Delay
Monitor	Monitoring Mode	45ºC (113ºF)	No delay
	In the Charger	45ºC (113ºF)	No delay
	Not monitoring / Not in the Charger	45ºC (113ºF)	No delay
Cuff Module	Connected to the Monitor	45ºC (113ºF)	No delay
	In the Charger	45ºC (113ºF)	No delay
	Not monitoring / Not in the Charger	45ºC (113ºF)	No delay
Power Pack	Connected to the Monitor	50ºC (122ºF)	No delay
	In the Charger	50ºC (122ºF)	No delay
	Not monitoring / Not in the Charger	50ºC (122ºF)	No delay

4.4.2 Equipment Alarms (Alerts)

Visual Display

The following table outlines the visual display when alerts are in progress:

Severity	Indicator Attributes	Toggle / Flash Speed	Duty Cycle
All Severities	Cyan (Blue)	Constant (ON)	100% ON

Audio Tones

The following table outlines the audio tones when alerts are in progress:

Severity	Melody[a]	Volume [dB]	Frequency (f_o) [Hz]	Duration (t_d) [ms]	Spacing (t_s) [ms]	Inter-Burst (t_b) [s]
High	e5.c5	68/63	659.255, 523.251	250	250	15

a. Melodies are defined as musical notes.

Note: There are no audio tones associated with low severity alerts.

Alarm Limits and Delays (factory default settings)

Chest Sensor Alerts	Limit(if applicable)	Audible Alert	Annunciation Delay
ECG Lead Failure	N/A	No	No delay
All ECG Lead Failure	N/A	No	No delay
Chest Sensor Disconnected	N/A	No	No delay
General Fault Detected	N/A	No	No delay
Multiple Connections	N/A	No	No delay
Temperature Sensor Fault	N/A	No	No delay
Accelerometer Fault - Chest Module	N/A	No	No delay
Accelerometer Fault - Upper Arm	N/A	No	No delay

Thumb Sensor Alerts	Limit (if applicable)	Audible Alert	Annunciation Delay (in seconds)
Thumb Sensor Off	N/A	No	< 30
Thumb Sensor Disconnected	N/A	No	No delay

Cuff Module Alerts	Limit (if applicable)	Audible Alert	Annunciation Delay (in seconds)
Low Battery	4% to 10%	No	No delay
Battery Empty	< 4%	No	No delay

Cuff Module Alerts	Limit (if applicable)	Audible Alert	Annunciation Delay (in seconds)
Check Cuff	N/A	No	No delay
Cuff Occluded	N/A	No	No delay
NIBP Unobtainable	N/A	No	No delay
Invalid Software Loaded	N/A	No	No delay
Pressure Accuracy Fault	N/A	No	No delay
General Fault Detected	N/A	No	No delay
Pressure Exceeded	300mmHg	Yes	No delay
Multiple Connections	N/A	No	No delay

cNIBP Alerts	Limit (if applicable)	Audible Alert	Annunciation Delay (in seconds)
Calibration Failed	N/A	N/A	No delay
Calibrate cNIBP	N/A	N/A	No delay
Hold Still	N/A	N/A	No delay

Wrist Monitor Alerts	Limit (if applicable)	Audible Alert	Annunciation Delay (in seconds)
Calibrate cNIBP	N/A	N/A	No delay
Low Battery	3 hours	No	No delay
Critical Low Battery	1 hour	No	No delay
Too Low to Monitor	10 minutes	No	No delay
Invalid Plug Connected	N/A	Yes	No delay
Audio System Failure	N/A	No	No delay
Wireless Radio Failure	N/A	No	No delay
All Sensors Disconnected	N/A	No	No delay
Accelerometer Failure	N/A	No	No delay
Shock Hazard	N/A	Yes	No delay
Patient Tampering (number of incorrect pin code entries)	5 invalid pin codes	No	No delay

ViSi Power Pack Alerts	Description of Annunciation	Audible Alert	Annunciation Delay (in seconds)
Power Pack Connected	1 Beep	Yes	No delay
Power Pack Disconnected	1 Beep	Yes	No delay
Power Pack Low Battery	Red LED Flashes (< 4% charge) Yellow LED Flashes (4%-10% charge)	No	No delay

ViSi Power Pack Alerts	Description of Annunciation	Audible Alert	Annunciation Delay (in seconds)
Battery Temp. Exceeds Limit	Red LED Solid and Continuous Beep Tone	Yes	No delay
Battery Current. Exceeds Limit	Red LED Solid and Continuous Beep Tone	Yes	No delay
Battery Pack Fault	Message on ViSi Monitor	Beep/Buzz on Power Pack ONLY	No delay

4.5 Environmental Conditions

Environmental Conditions for all ViSi Mobile Components (Monitor, Cuff Module, Chest Sensor, Cuff, Thumb Sensor, Power Pack)		
Condition	**Storage (Packaged / Unpacked)**	**Operating (Unpackaged)**
Temperature	-20^{o}C to +55^{o}C (50^{o}C for NIBP) -4^{o}F to +131^{o}F (122^{o}F for NIBP)	0^{o}C to +40^{o}C / 32^{o}F to +122^{o}F Battery Charger: 0^{o}C to +40^{o}C
Humidity	15% to 95% non-condensing (90% for NIBP)	10% to 95% non-condensing (90% for NIBP) (15% to 95% non-condensing for Power Pack)
Atmospheric Pressure Range	107 kPa to 50 kPa 803 mmHg to 375 mmHg 1.06 atm to 0.49 atm	107 kPa to 70 kPa 803 mmHg to 525 mmHg 1.06 atm to 0.69 atm

The ViSi Mobile Monitoring System may not perform to specification if stored or shipped outside the specified temperature range.

4.6 Compliances

Observe any national regulations on the qualification of the testing personnel and suitable measuring and testing facilities. *See "User/Preventative Maintenance" on page 105.* for a list of required tests.

4.6.1 Federal Communications Commission (FCC)

The equipment device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received including interference that may cause undesired operation.

Changes or modifications not expressly approved by Sotera Wireless, Inc. could void the user's authority to operate the equipment. Manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment.

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna
- Increase the separation between the equipment and receiver
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected
- Consult the dealer or an experienced radio/TV technician for help

This device complies with Industry Canada license-exempt RSS standard(s). Operation is subject to the following two conditions: (1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

Class B digital device notice / "CAN ICES-3 (B)/NMB-3(B)".

This equipment complies with the FCC/IC radiation exposure limits set fourth for portable transmitting devices operation in a controlled environment. End users must follow the specific operating instructions to satisfy RF exposure compliance.

The equipment should only be used where there is normally at least 22.651mm separation between the antenna and all person/user.

This transmitter must not be co-located or operated in conjunction with any other antenna or transmitter.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

4.6.2 Electromagnetic Compatibility (EMC) Specifications

Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. Operate your monitoring equipment according to the EMC information provided in this manual. Portable and mobile radio frequency (RF) communications equipment can affect medical electrical equipment.

Consult your Biomed department or vendors for assistance in identifying EMC compliance status of other medical devices when using the ViSi Mobile Monitoring System or Power Pack.

Accessories Compliant with EMC Standards

All accessories (e.g. ViSi Mobile Charger) comply with either IEC 60601-1-2 or IEC 60950-1.

Using accessories other than those specified may result in increased electromagnetic emission or decreased electromagnetic immunity of the monitoring equipment.

4.6.3 Electromagnetic Emissions

The ViSi Mobile Monitor is suitable for use in the electromagnetic environment specified in the table below. Ensure that the Monitor is used in such an environment.

Emissions Test	Compliance	Avoiding Electromagnetic Interference
Radio Frequency (RF) emissions	Group 1	The ViSi Mobile Monitor uses RF energy only for its internal function[a]. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The ViSi Mobile Monitor is suitable for use in all establishments other than domestic and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations IEC 61000-3-3	N/A	

a. The battery operated ViSi Mobile Monitor contains a 2.4 GHz DSSS transmitter for the purpose of wireless communication. The radio is excluded from the EMC requirements of IEC 60601-1-2, but should be considered when addressing possible interference issues between this and other devices.

4.6.4 Electromagnetic Immunity

The ViSi Mobile Monitor is suitable for use in specified electromagnetic environments. The user must ensure that it is used in the appropriate environment as described below.

Immunity Test	IEC 60601-1-2		Electromagnetic Environment Guidance
	Test Level	**Compliance Level**	
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient / burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical medical and/or hospital environment.
Surge IEC61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical medical and/or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% UT (>95% dip in UT) for 0.5 cycles	<5% UT (>95% dip in UT) for 0.5 cycles	
	40% UT (60% dip in UT) for 5 cycles	40% UT (60% dip in UT) for 5 cycles	
	70% UT (30% dip in UT) for 25 cycles	70% UT (30% dip in UT) for 25 cycles	
	<5% UT (>95% dip in UT) for 5 sec	<5% UT (>95% dip in UT) for 5 sec	
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical hospital environment.

In the above table, UT (Unit in Test) is the ViSi Mobile Monitoring System.

4.6.5 Recommended Separation Distance

The ViSi Mobile Monitor may be temporarily interrupted by UHF RFID Systems (860-960MHz).

2-way radios may cause waveform distortion when placed within 1 foot of the ViSi Mobile Monitor.

Some brands of television may cause temporary waveform distortion and data loss when placed within 6 feet of the ViSi Mobile Monitor.

Portable and mobile RF communications equipment should be used no closer to any part of the ViSi Mobile Monitor, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with this symbol:

In the following table, P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Immunity Test	**IEC 60601-1-2 Test Level**	**ViSi Mobile Monitoring System Compliance Level**	**Electromagnetic Environment Guidance**
Conducted RF IEC 61000-4-6	3 V_{RMS} 150 kHz to 80 MHz	3 V_{RMS}	Recommended separation distance: $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	Recommended separation distance: 80 MHz to 800 MHz 80 MHz to 800 MHz $d = 3.5\sqrt{P}$ 800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$ 2.0 to 2.3 GHz for short radio $d = 7.0\sqrt{P}$

Field strengths from fixed transmitters, such as base stations for radio (cellular, cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ViSi Mobile Monitor is used exceeds the applicable RF compliance level above, the Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the Monitor.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

From Portable and Mobile RF Communication Equipment

The ViSi Mobile Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the Monitor as recommended below, according to the maximum output power of the communications equipment.

In the following table, P is the maximum power output rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).

Frequency	**150 kHZ to 80 MHz**		**80 MHz to 800 MHz**		**800 MHz to 2.5 GHz**	
Equation	**$d = 1.2\sqrt{P}$**		**$d=1.2\sqrt{P}$**		**$d=2.3\sqrt{P}$**	
Rated max. output power of transmitter	**Separation Distance**		**Separation Distance**		**Separation Distance**	
	(m)	**(ft)**	**(m)**	**(ft)**	**(m)**	**(ft)**
0.01 W	0.1	0.4	0.1	0.4	0.2	0.8
0.1 W	0.4	1.2	0.4	1.2	0.7	2.4
1 W	1.3	3.9	1.3	3.9	2.3	7.5
10 W	3.8	12.4	3.8	12.4	7.3	23.9
100 W	12.0	39.4	12.0	39.4	23.0	75.5

Electrosurgery Interference/Defibrillation/Electrostatic Discharge

The equipment returns to the previous operating mode within 10 seconds without loss of any stored data. Measurement accuracy may be temporarily decreased while performing electrosurgery or defibrillation. This does not affect patient or equipment safety. Do not expose the equipment to x-ray or strong magnetic fields (MRI).

Fast Transients/Bursts

The equipment will return to the previous operating mode within 30 seconds without loss of any stored data.

4.6.6 Standards

Agency Compliances
• CAN/CSA C22.2 No 60601-1, Part 1: General requirements for basic safety and essential performance • IEC 60601-1:2005 Medical electrical equipment - Part 1: General requirements for safety (EN 60601-1:2006) • IEC 60601-1-2:2007, Med. Elect. Equipment – Part 1-2: General requirements for safety – Collateral standard: EMC – Req. and tests. • IEC 60601-1-6:2010, Medical electrical equipment – Part 1-6: General requirements – Collateral standard: Usability. • IEC 60601-1-8:2012, Medical electrical equipment – Part 1-8: Gen. req. – Col. Std. Gen. requirements, tests and guidance for alarm systems • IEC 60601-2-27:2011, Medical electrical equipment, Part 2-27: Particular requirements or the safety, including essential performance, of ECG monitoring equipment (except 208.6.6.2.103). • IEC 80601-2-30:2009, Medical electrical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of auto. cycling non-invasive BP monitoring equipment. • IEC 60601-2-49:2011, Medical electrical equipment - Part 2-49: Particular requirements for the basic safety and essential performance of multi-function patient monitoring equipment. • ISO 80601-2-61:2011, Medical electrical equipment - Particular requirements for the basic safety and essential performance of pulse oximeter equipment for medical use. • IEC 62304:2006, Medical device software – Software life cycle processes • IEC 62366:2007, Medical devices – Application of usability engineering to medical devices.

4.7 Wireless Network Risk Mitigation

Reference: ISO 80001-1

ViSi Mobile System utilizes the Responsible Organization's wireless IT network to communicate between individual ViSi Mobile Monitors connected to patients and the ViSi Appliance. Physiologic data and alarms originating from the ViSi Mobile Monitors are transmitted over the IT network to the ViSi Mobile Remote Viewer where supplemental alarm notification occurs. Reliability of the IT network is essential in ensuring the supplementary alarm notification meets the intended use.

Other RF radiating devices (such as high powered RFID readers and Bluetooth devices) that are in close proximity with the ViSi Mobile Monitor may interfere with the Monitor's wireless communications. During such interference, the Monitor continues to monitor and will alarm locally. If wireless communication is affected when using the Monitor in close proximity with another RF radiating device, move the other device away from the Monitor or discontinue use of the other device.If you have any concerns regarding a cyber security breach or vulnerability, contact Sotera Wireless, Inc. or an authorized Sotera Wireless, Inc. representative in your area.

Perform a risk assessment and verification before implementing a change or modification to the IT infrastructure. Changes to IT network configurations can compromise continuous vital signs monitoring and alarm delivery. on page 12

4.7.1 Risk Analysis Summary

- The ViSi Mobile Monitors are the source of all alarms and alerts.
- The ViSi Mobile Remote Viewer provides a supplemental alarm notification. When connectivity is present audio alarms are deferred to the ViSi Mobile Remote Viewer.
- In the event that network connectivity is lost, all audio alarms are annunciated at the ViSi Mobile Monitors. A connectivity lost alert is annunciated at the ViSi Mobile Remote Viewer.

4.7.2 Residual Risks

Loss of network connectivity will result in failure in supplemental alarm notification to the ViSi Appliance and ViSi Mobile Remote Viewer. Management of this risk is the responsibility of the Responsible Organization for the IT Network. This risk is minimized with the following mitigations:

Sotera Responsibilities

- Sotera Inc network assessment prior to installation.
- Sotera Inc verification that the Responsible Organization network meets ViSi Mobile System connectivity requirements at the time of installation.
- Hand over protocol with all settings/configurations as installed and configured (Training)

Responsible Organization Responsibilities

- Conduct a risk assessment of the IT Network prior to installation and mitigate technical risk.
- Maintain backup and emergency power resources for ViSi System network components.
- Maintain network configuration post installation of the ViSi Mobile System.

Notify Sotera Wireless, Inc. prior to making modifications to the network, including configuration changes that could potentially compromise the IT Network as verified at the initial installation of the ViSi System.

For support contact Sotera Wireless, Inc. or an authorized Sotera Wireless, Inc. representative in your area.

- Notes -

Product Modes

5.1 Introduction

Customer site Bio Meds will be able to access ViSi Mobile's different Product Modes using an 8-digit PIN. The 8-digit PIN is available upon request by calling Sotera Wireless' Customer Service located page 103.

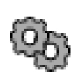
Bio Meds will be the only ones who will be able to access the different Product Modes.

Bio Meds must complete training by Sotera Wireless, Inc. before utilizing any of these functions.

5.2 Monitoring/Non-Monitoring Modes

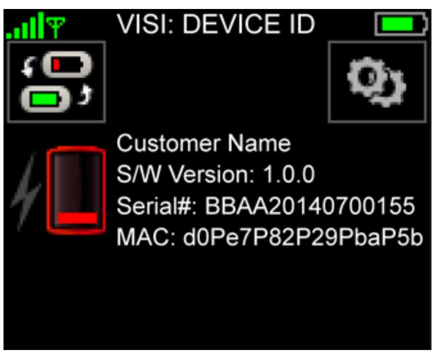
In order to access Product Modes, the Monitor must be in "Non-Monitoring" Mode.

When the ViSi Mobile Monitor is in "Non-Monitoring" Mode, a "gear" symbol wll be displayed in the upper right side of the Monitor.

	Enabled	Disabled
Non-Monitoring Mode		

Monitoring Mode

Non-Monitoring Mode



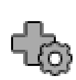
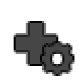
Non-Monitoring Mode - Enabled
Battery Charged

Non-Monitoring Mode - Disabled
Battery Critically Low

Note: **When the Monitor's battery becomes critically low, the "Modes" and "Device Swap" menu options become disabled.**

5.3 Bio Med Mode

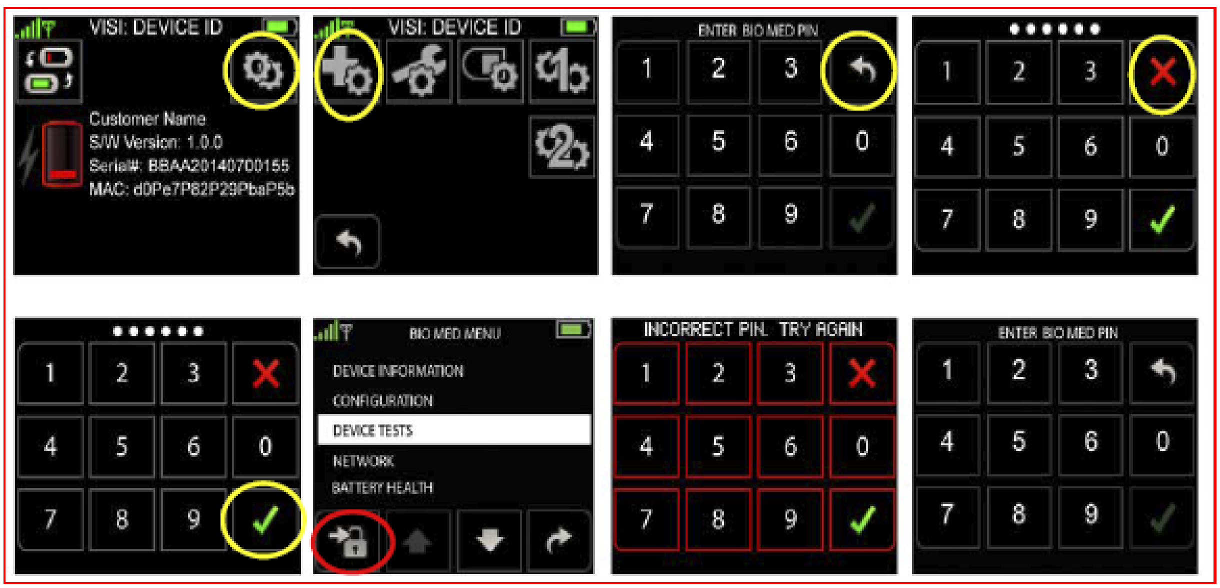
The "Bio Med" Mode allows the Bio Med to access select Monitor settings.

	Enabled	Disabled
Bio Med Mode		

Note: **The ViSi Mobile Monitor must be in "Non-Monitoring" Mode in order to access this funtion. Bio-Med must use the 8-digit PIN code given by Sotera Wireless' Customer Service.**

Accessing Bio Med Mode

1. Touch the “Mode” symbol.
2. Select “Bio Med” symbol.
3. Enter “Bio Med” 8-digit PIN.
4. If the “Back” button is selected, the screen will revert back to the “Select Mode” screen.
5. Once the first number of the PIN are entered, the “Back” button will be replaced with the “Cancel” button.
6. As additonal numbers are added, a white dot will appear for each numeric entered.
7. If the “Cancel” button is pressed, all already entered numbers will be erased and the “Cancel” button will revert back to the “Back” button.
8. Once a correct 8-digit PIN has been entered and the “Confirm” button selected, the “Bio Med” screen will appear.
9. If an incorrect 8-digit PIN has been entered, the screen will flash red for approximately three seconds. Numerics page will be displayed to try again.



The “Bio Med” Mode session will end once any one of the following occurs:

a. The “Lock” button is touched.

b. A thumb sensor is connected to the Monitor.

c. The Monitor is placed into a charger.

Bio Med Mode allows access to erase Network Configurations on the Monitor. If Network Configurations accidentally get erased, the Monitor will have to be returned to Sotera Wireless, Inc.to be reloaded again. Do NOT erase Network Configurations.

5.4 Enable/Disable Skin Temperature

The Skin Temperature Vital Sign can be enabled or disabled while in “Bio Med” Mode. This setting can only be changed for stand-alone Monitors. All networked Monitors will become configured by the .XML file once the Monitors re-connect to the network.

- *Notes* -

Enable/Disable Skin Temperature

6. Updating Remote Viewer Settings

6.1 Introduction

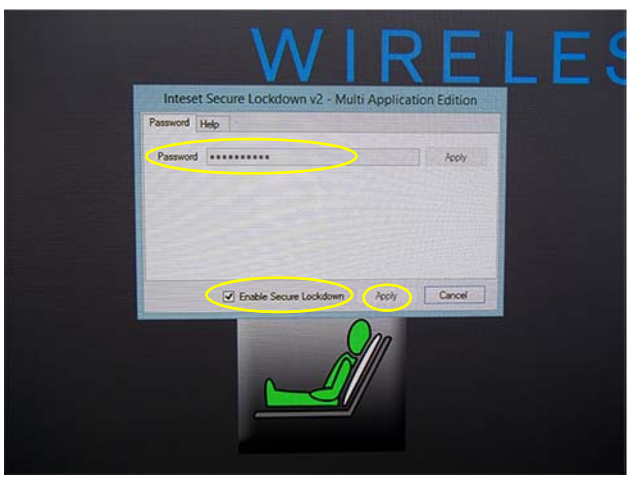
Certain settings on the ViSi Remote Viewer can be changed by the hospital’s Bio Med.

Bio Meds must complete training by Sotera Wireless, Inc. before utilizing any of these functions.

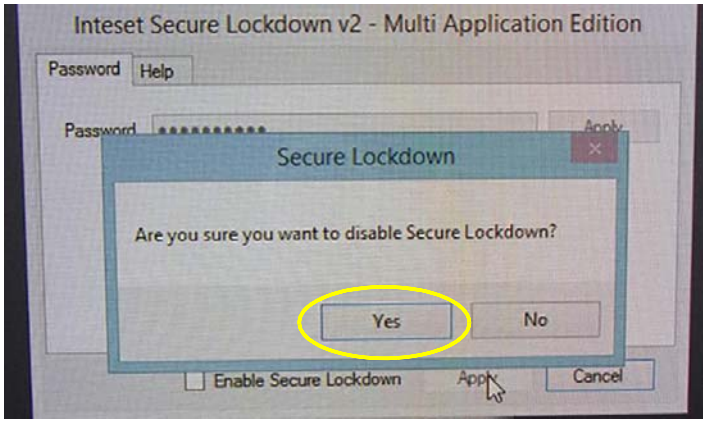
6.2 Disable Secure Lockdown

To disble Secure Lockdown:

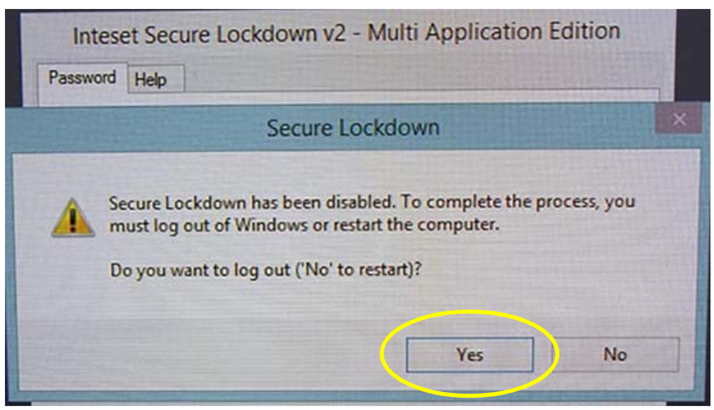
1. Simultaneously press “Alt, Shift and S” keys on the keyboard
2. Enter “s0t3r@9444” for the “Password”
3. Un-check the “Enable Secure Lockdown” box and Click “Apply”



4. When asked "Are you sure you want to disable Secure Lockdown", Click "Yes"



5. When asked "Do you want to log out (No to restart)?" Click "Yes"



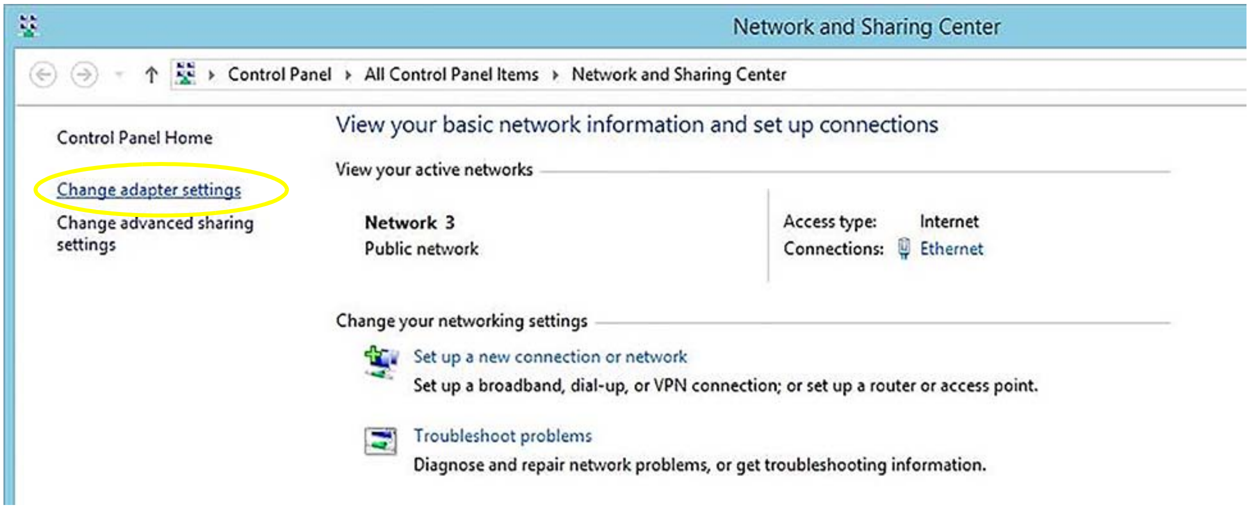
6.3 Disable (Wireless Settings) WLAN NIC Adaptor

To disable the Wireless Settings/WLAN NIC Adaptor:

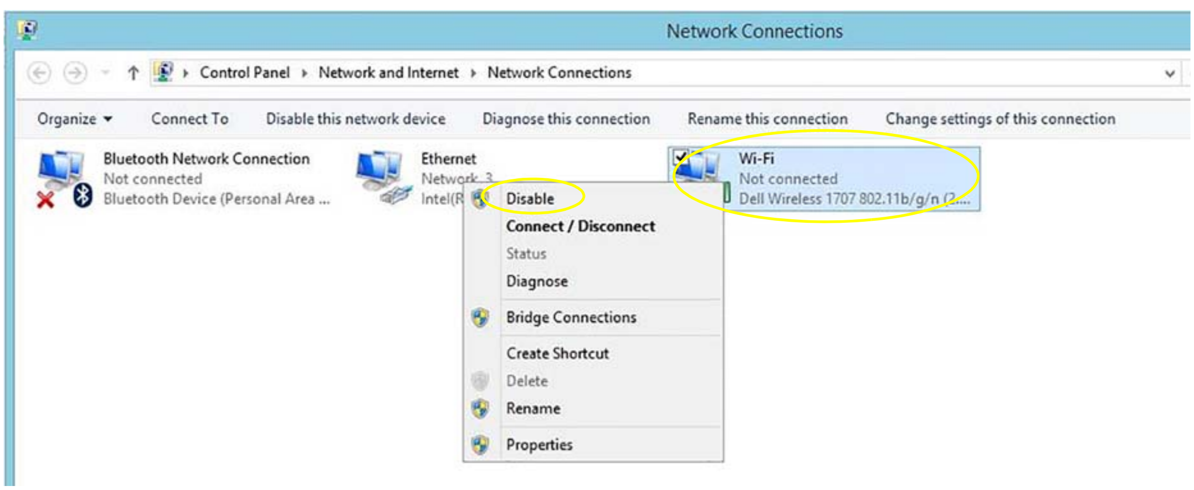
1. Locate the “Network 3 Internet Access” icon on the tool bar

2. Click “Open Network and Sharing Center”

3. Click "Change adapter settings" link on the left



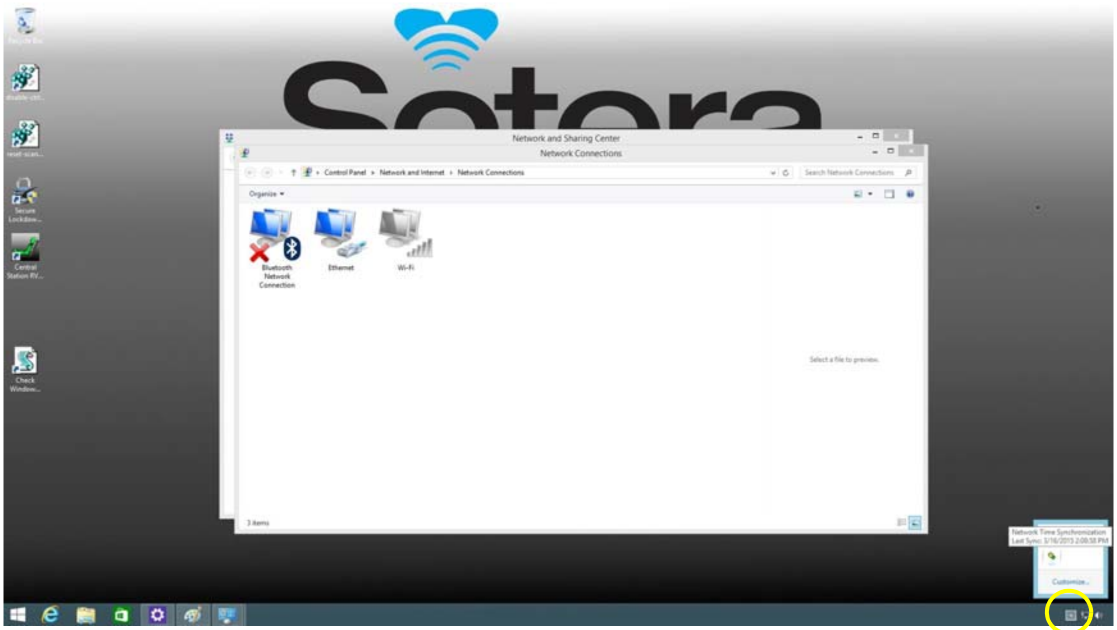
4. Right Click on the adapter for the wireless NIC
5. Click "Disable" in drop down menu



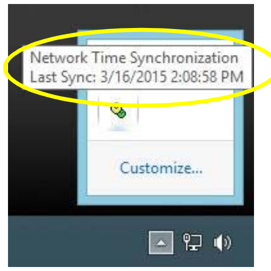
6.4 Configure NTP Client

To configure the NTP Client:

1. Locate the NTP client application in the hidden icon notifcation area in the lower right hand corner of screen
2. Click the “Show Hidden Icon” arrow

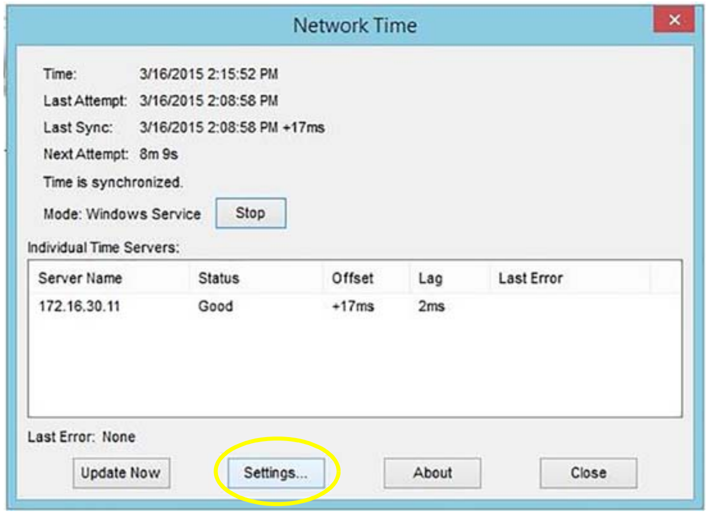


3. Click on “Network Time Synchronization”

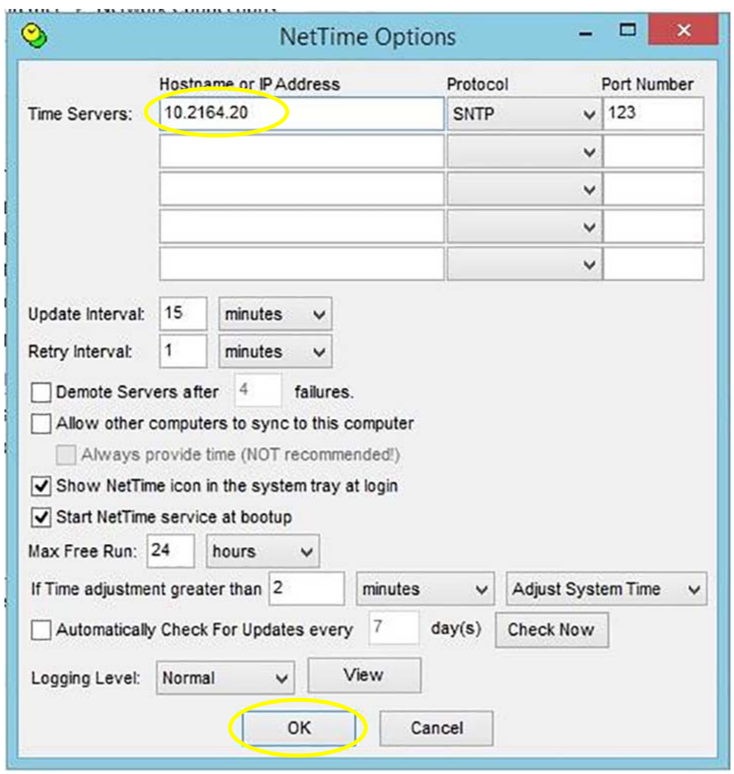


4. Click the “Settings” button along the bottom of display box

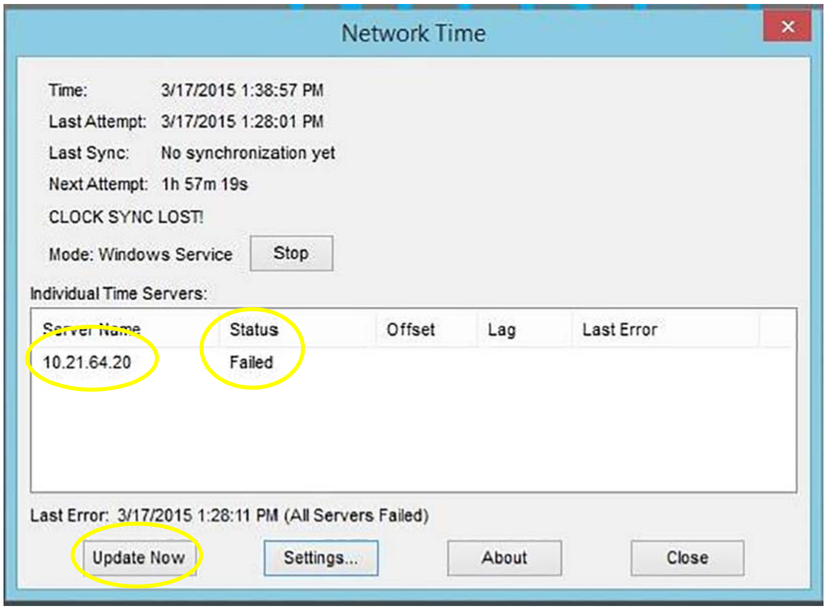
Configure NTP Client



5. Enter "IP Address" in first line of "Time Servers"
6. Click "OK" on the bottom of display



7. Click "Update Now" on the bottom of the dislpay box to test connectivity



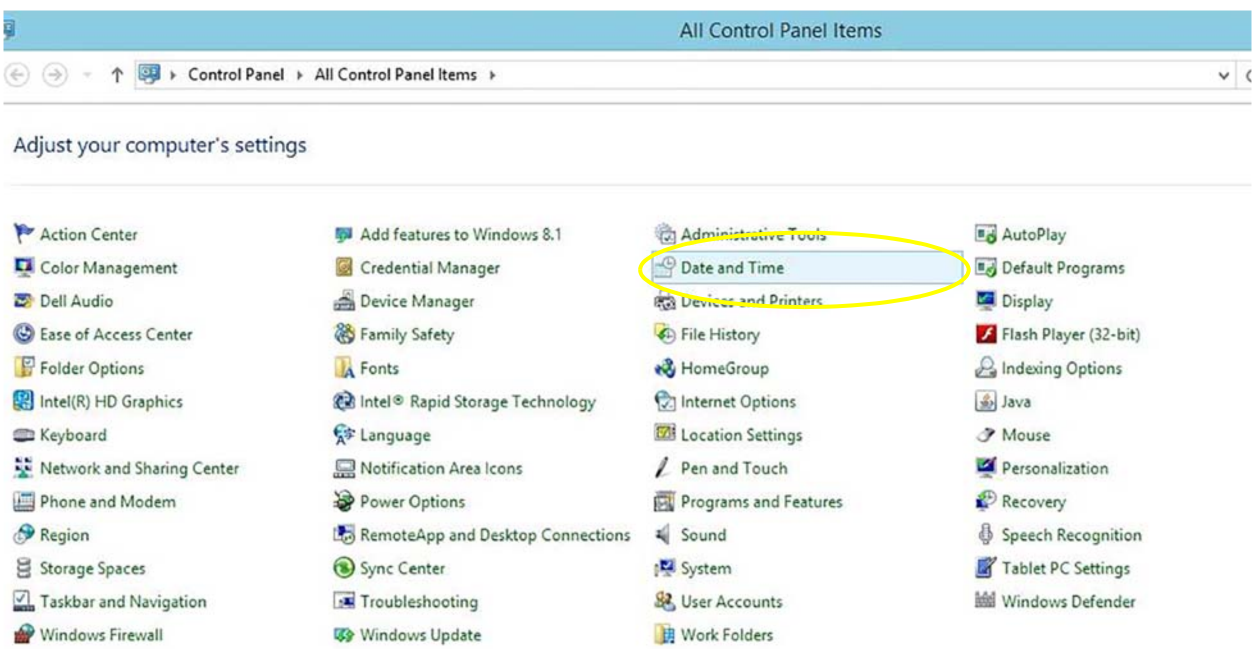
Note: If status reads "Failed", the IP Address is incorrect. Steps in Section 6.4Configure NTP Client will need to be performed again until Status is "Passed".

6.5 Disabling Synch with Network Time and Change Time Zone

1. Locate "Settings" icon in lower right corner of screen
2. Click on the "Settings" icon

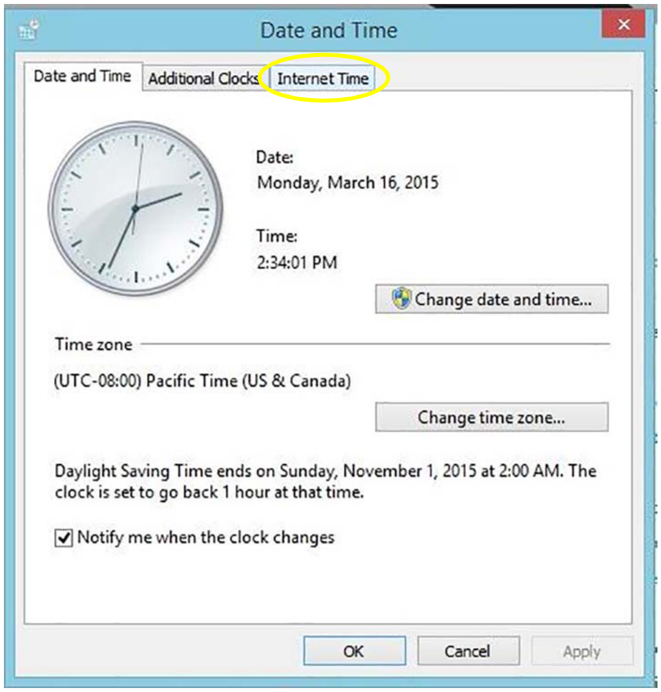
3. Click "Control Panel" on right side of screen.

4. Click on "Date and Time" option

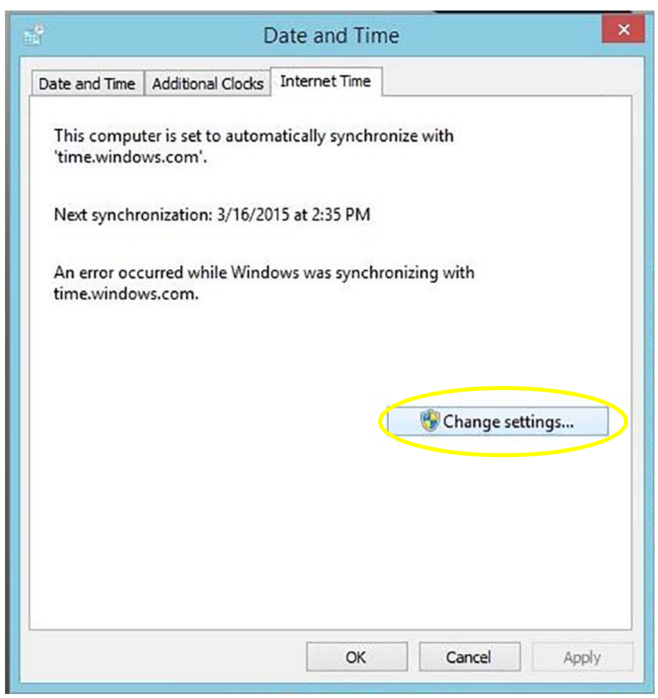


Disabling Synch with Network Time and Change Time Zone

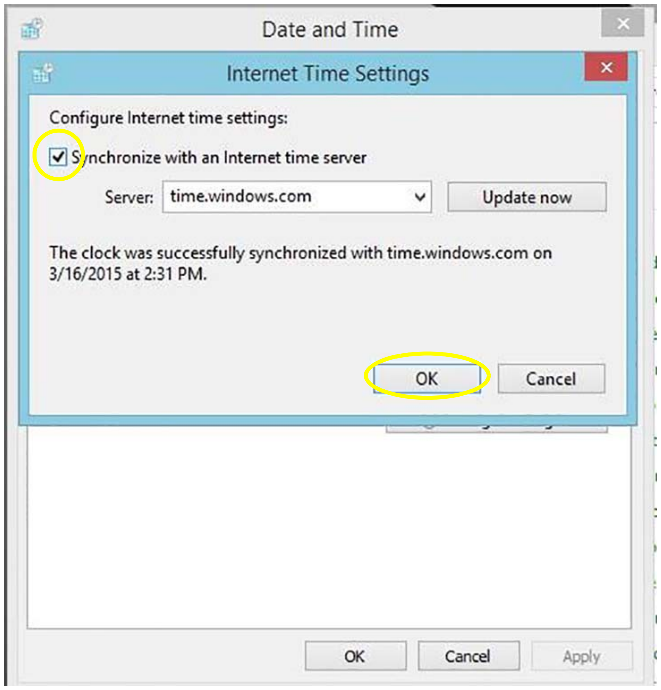
5. Click on the “Internet Time” Tab



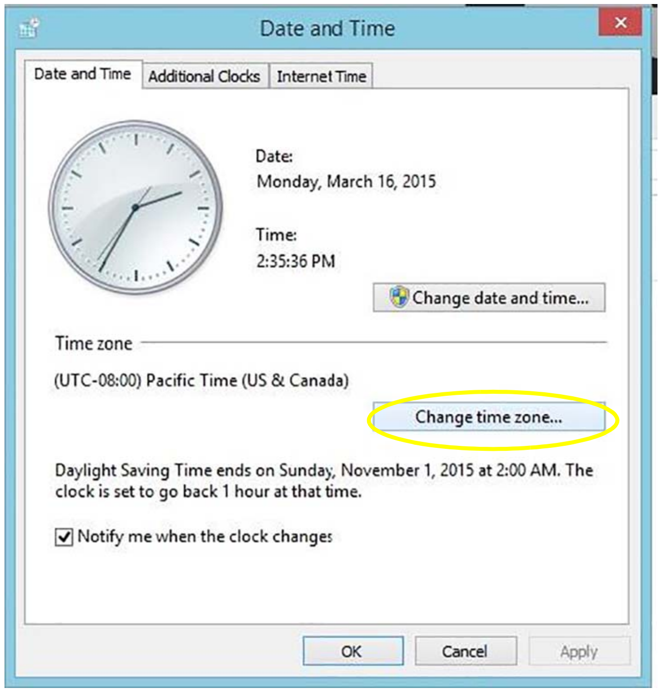
6. Click on “Change settings...” button in the middle of display screen



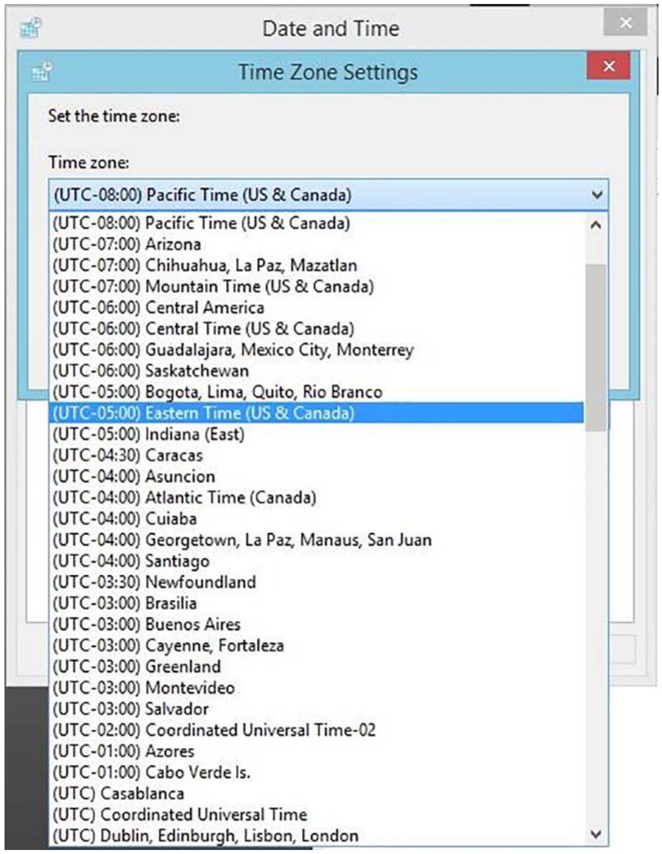
7. Un-check the "Synchronize with an Internet time server" box
8. Click "OK"



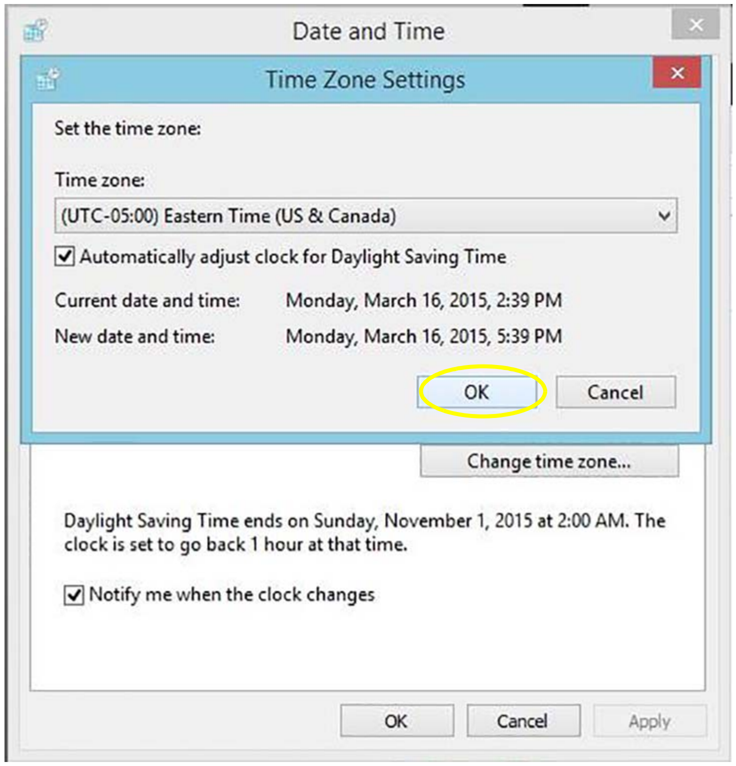
9. Click "Change time zone" button



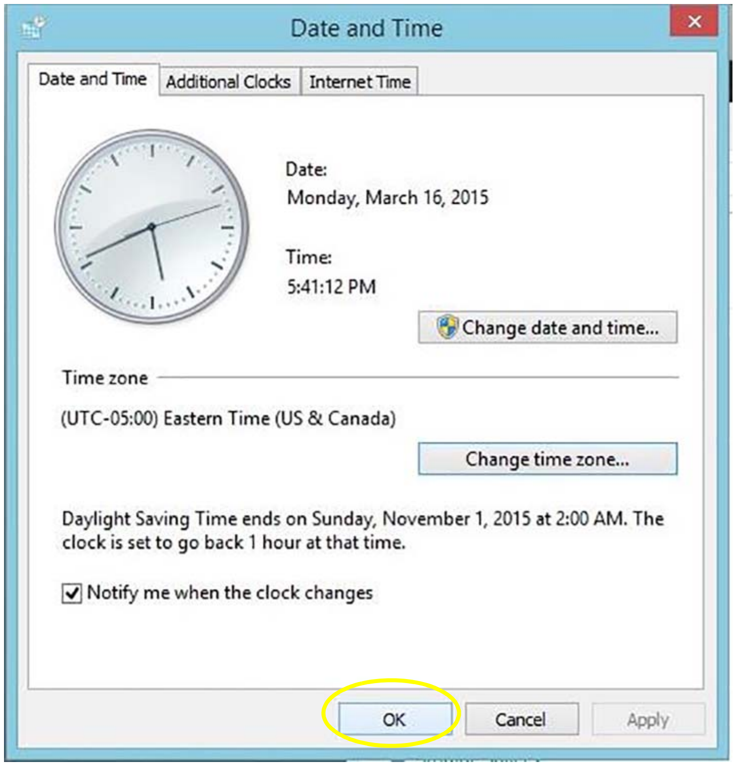
10. Use the drop down menu to select the desired time zone



11. Click “OK” to accept desired “Time zone settings”



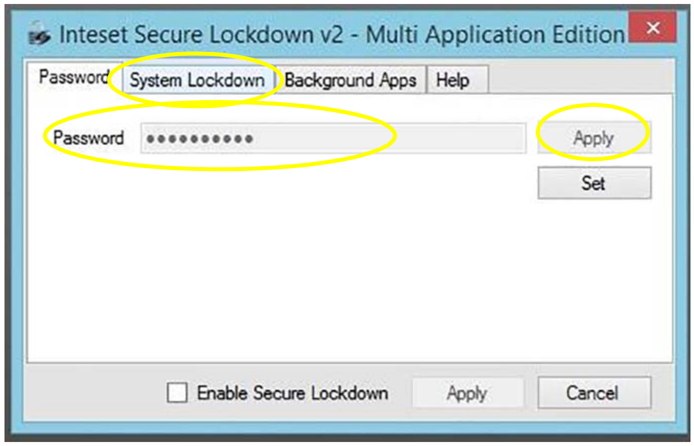
12. Click “OK” to confirm Time zone changes



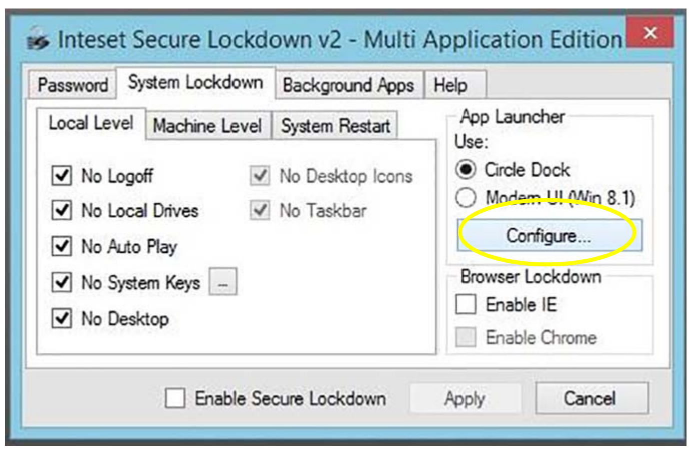
6.6 Configure Inteset Secure Lockdown v2

To configure Inteset Secure Lockdown v2 with the Server IP Address:

1. Simultaneously press “Alt, Shift and S” keys on the keyboard
2. Enter “s0t3r@9444” for the “Password”
3. Click “Apply” to the right of the “Password”
4. Click on the “System Lockdown” tab

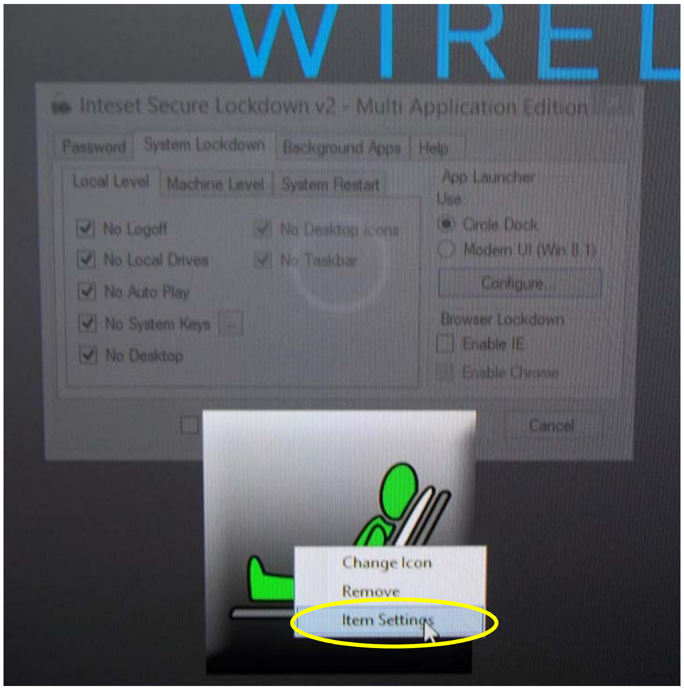


5. Click "Configure" button



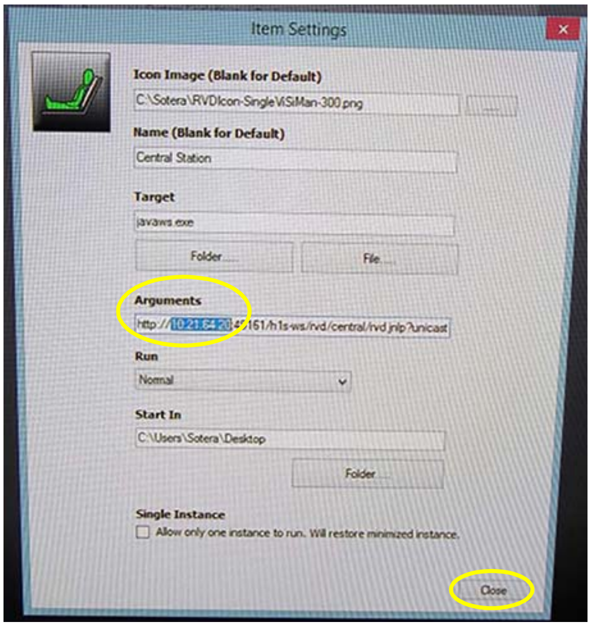
The Patient icon will now be displayed.

6. Right click on the "Patient" icon
7. The "Menu" drop down will apper; click "Item Settings" on the bottom of list



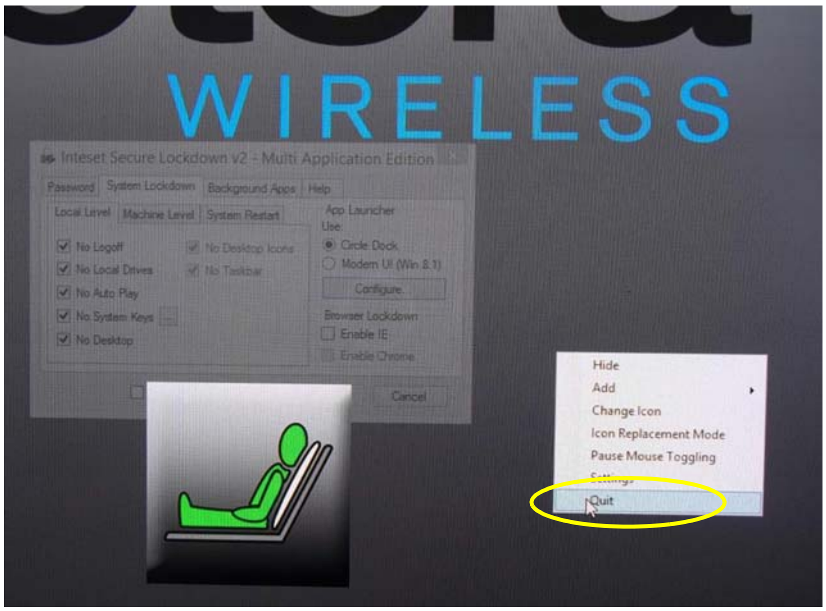
Update the IP Address.

8. Hightlight the "IP Address" under "Arguments" section for the "IP Address" that should be changed
9. Enter in the NEW "IP Address" by typing over the OLD highlighted "IP Address"
10. Click "Close"



ONLY change the IP Address. Do not delete any other information in this section. Exit out of this display screen without saving if there is any doubt that any other information has been changed. Repeat step again to make the required change.

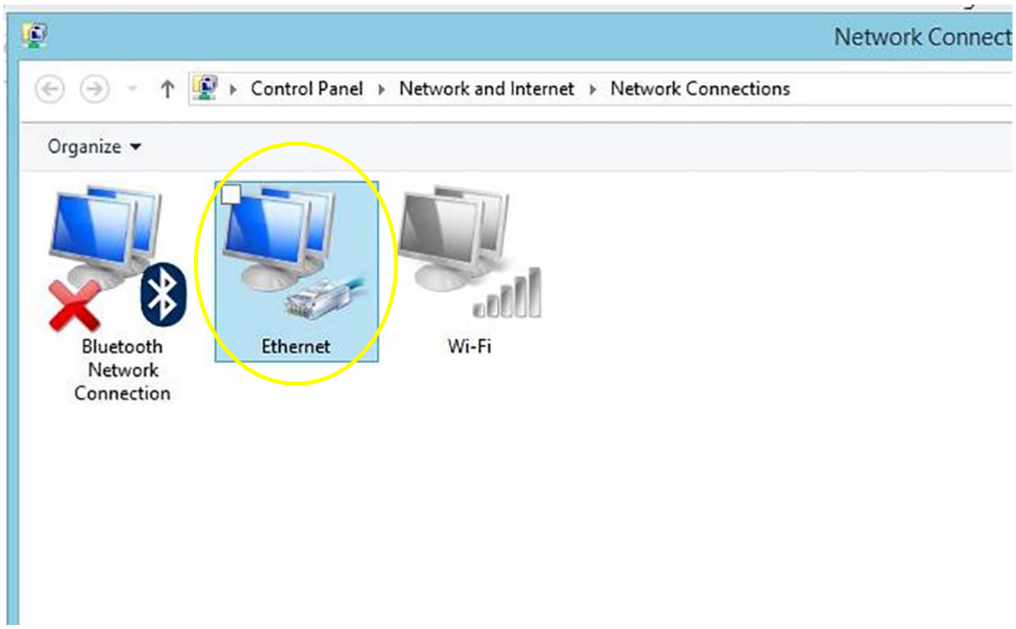
11. Access the menu by right clicking on the desktop
12. Select and click “Quit” to exit



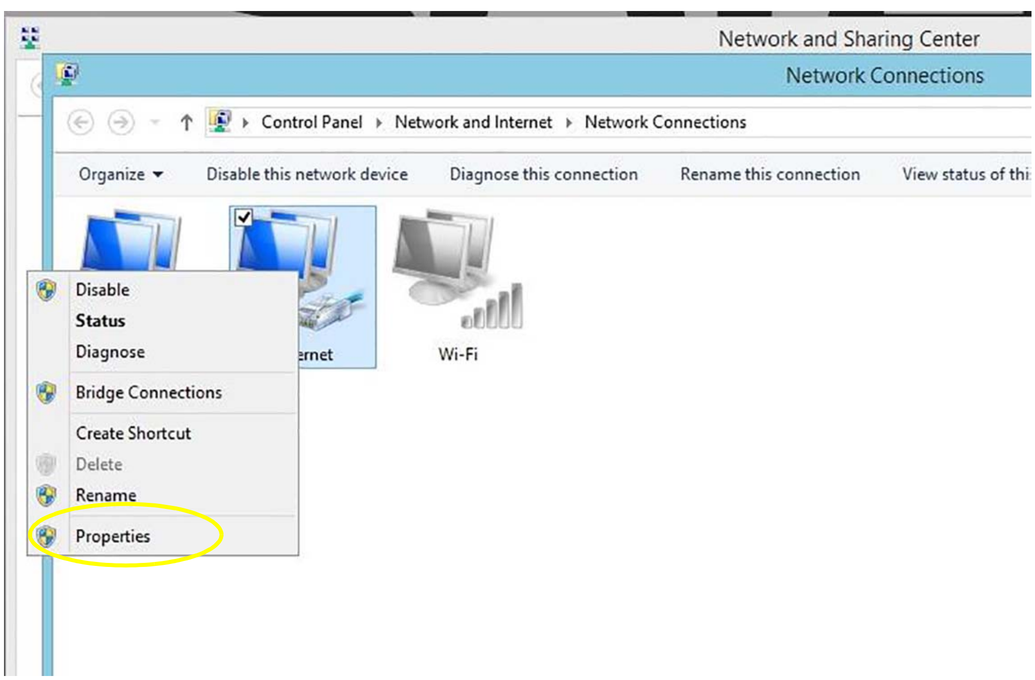
6.7 Verify DHCP or Update Static IP Address

To verify the DHCP or update the Static IP Address:

1. Access the "Network Connections" display (See steps 2.Click "Open Network and Sharing Center" on page 75 and 3.Click "Change adapter settings" link on the left on page 76)
2. Right Click on "Ethernet" icon



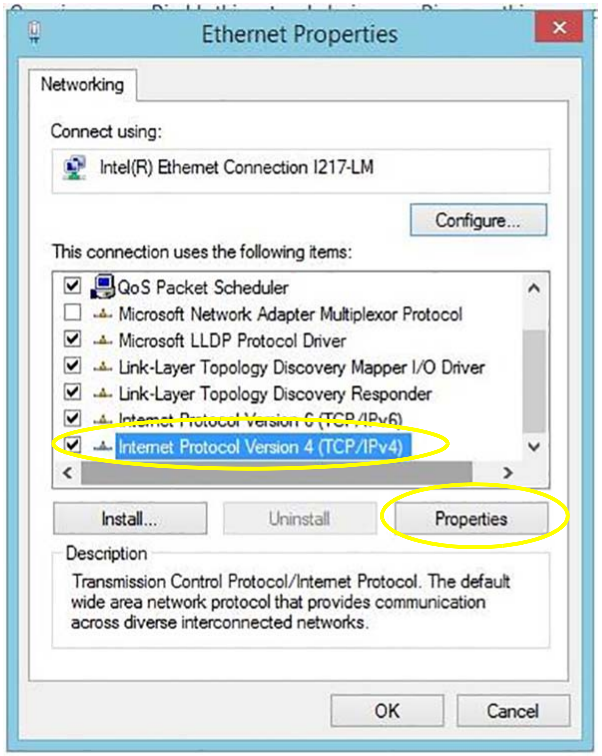
Click on "Properties"



Ethernet Properties will now be displayed.

3. Select "Internet Protocol Version 4 (TCP/IPv4) in drop down

4. Click "Properties"



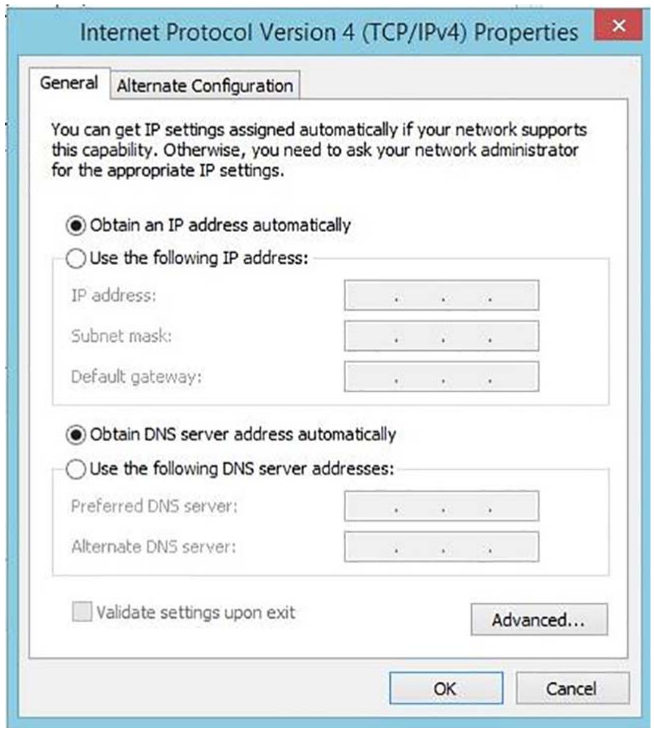
Internet Protocol Version 4 (TCP/IPv4) will be displayed.

DHCP is the default setting and can be confirmed by checking the following:

1. "Obtain an IP Address automatically" radio button is selected
2. "Obtain DNS server address automatically" radio button is selected
3. Click "Cancel" after confirmation

If the Static IP Address needs to change:

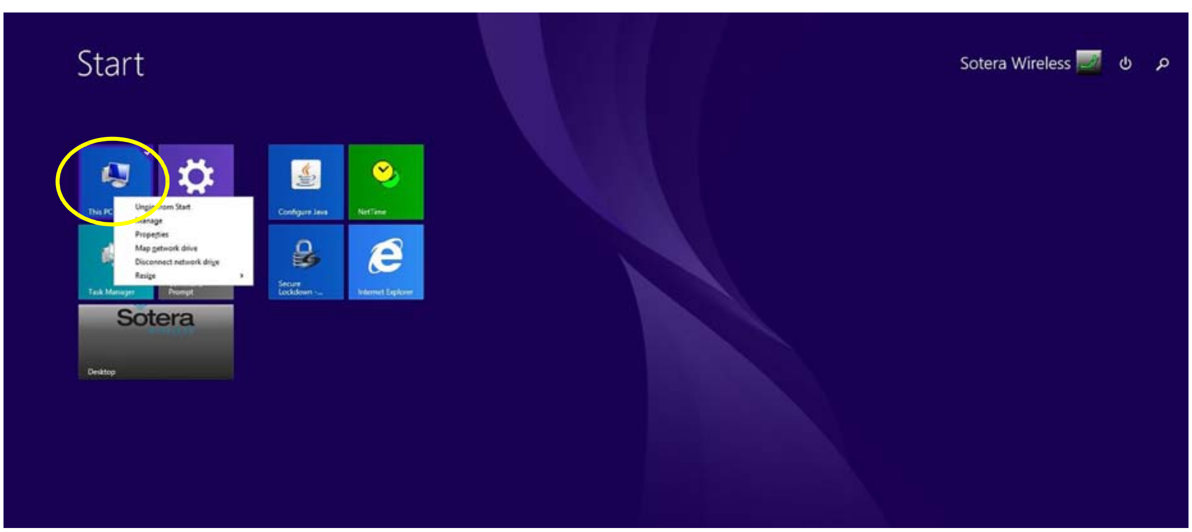
1. Click "Use the following IP Address" radio button
2. Enter the "IP Address", "Subnet Mask", and "Default Gateway" in fields below that section
3. Click "Use the following DNS server addresses" radio button
4. Enter "Preferred DNS server" and/or "Alternate DNS server" addresses in fields below that section
5. Click "OK" after change



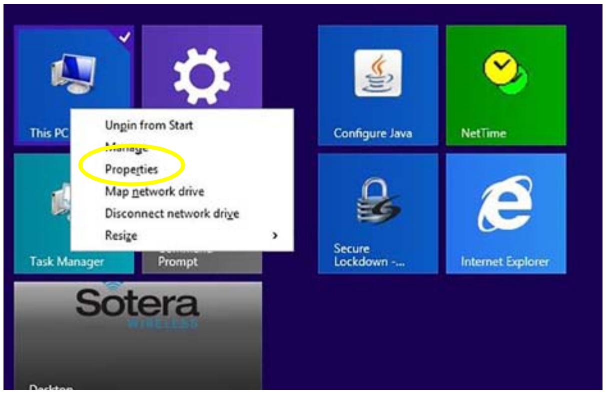
6.8 Change Hostname

To change the hostname:

1. Locate “This PC” icon on the desktop
2. Right click “This PC” icon to access the menu
3. Select “Properties”

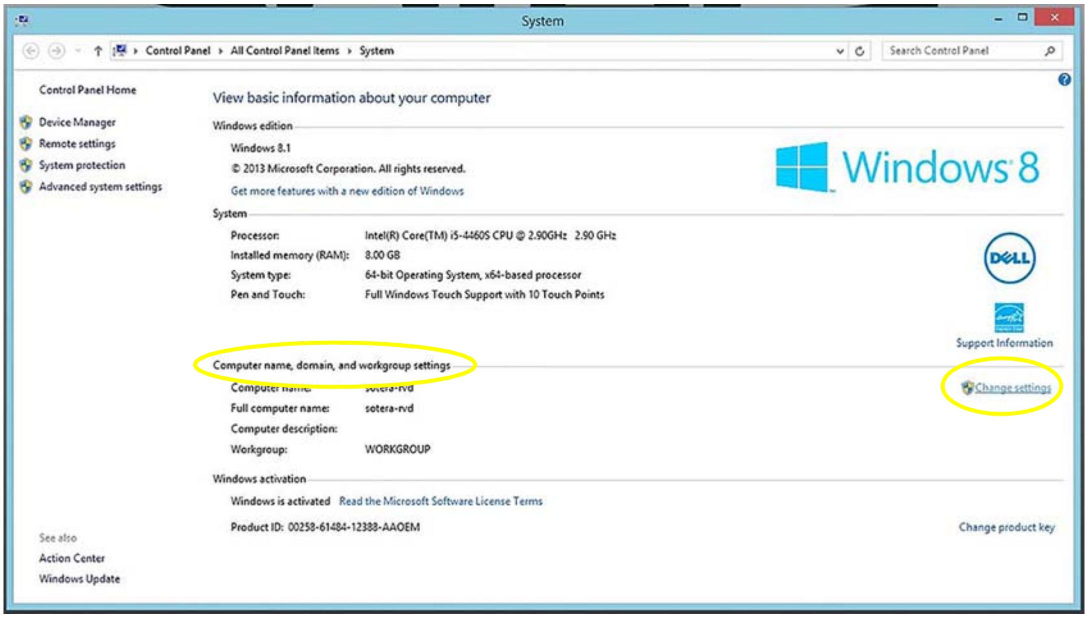


Change Hostname



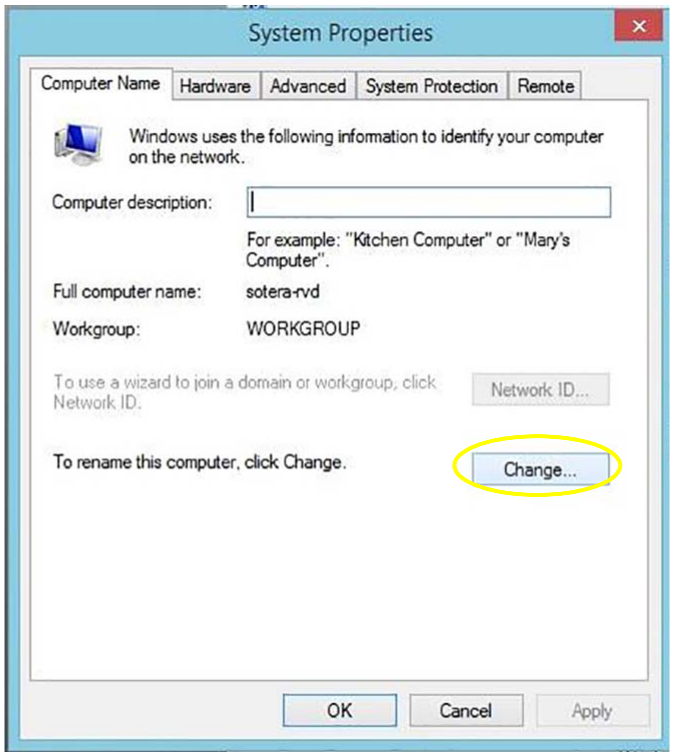
The “System” display page will come up.

1. Locate the “Computer name, domain and workgroup settings” section on page
2. Click the “Change settings” link to the right



The “System Properties” display page will come up.

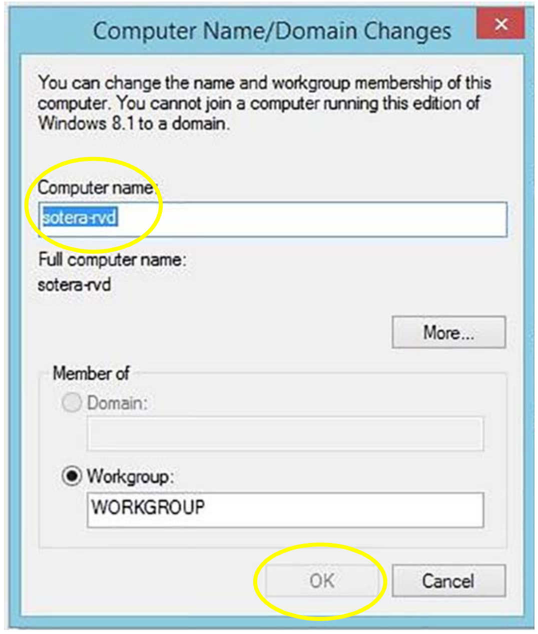
1. Click the "Change" button



The "Computer Name/Domain Changes" display page will come up.

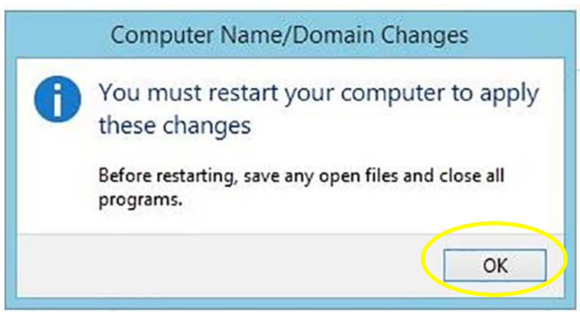
1. Enter new "Computer Name"
2. Click "OK"

Change Hostname



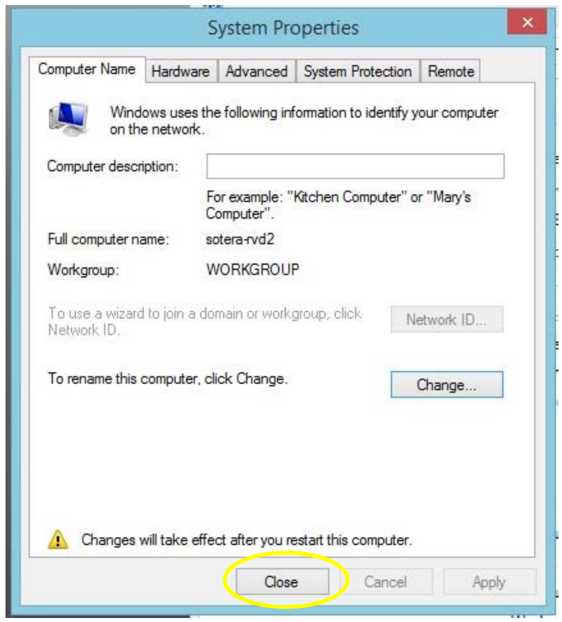
The "Computer Name/Domain Changes" Restart Computer prompt will pop-up.

1. Click "OK" to restart computer for changes to apply



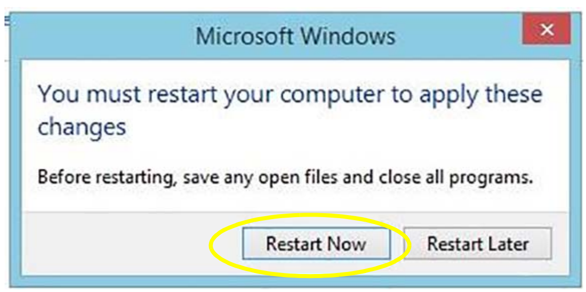
"System Properties" display will come up.

1. Click “Close”



“Microsoft Windows” display will come up.

1. Click “Restart Now” for computer to restart and apply name change



Note: You must restart computer in order for changes to take effect.

6.9 Disable-CTRL

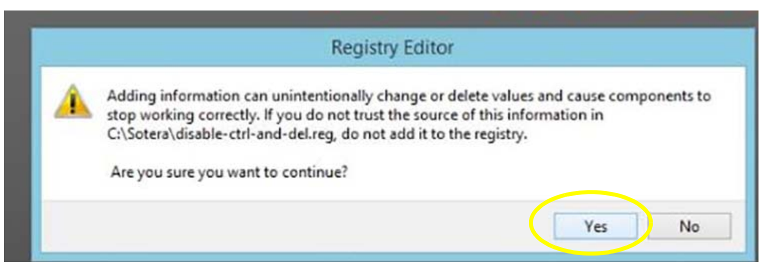
To disable CTRL:

1. Locate the “disable-ctrl” icon
2. Double click on the “disable-ctrl” icon

Disable-CTRL

The first “Registry Editor” dialog box will now be displayed.

1. When asked “Are you sure you want to continue”, Click “Yes”



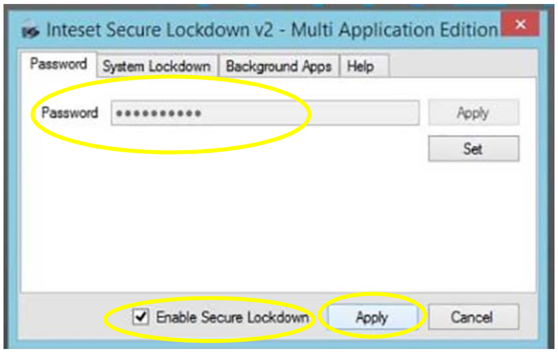
The second “Registry Editor” dialog box will now be displayed.

1. Click “OK” to the “The keys and values contained in C:\Sotera\disable-ctrl-and-del.reg have been successfully added to the registry” message displayed

6.10 Re-activate Secure Lockdown

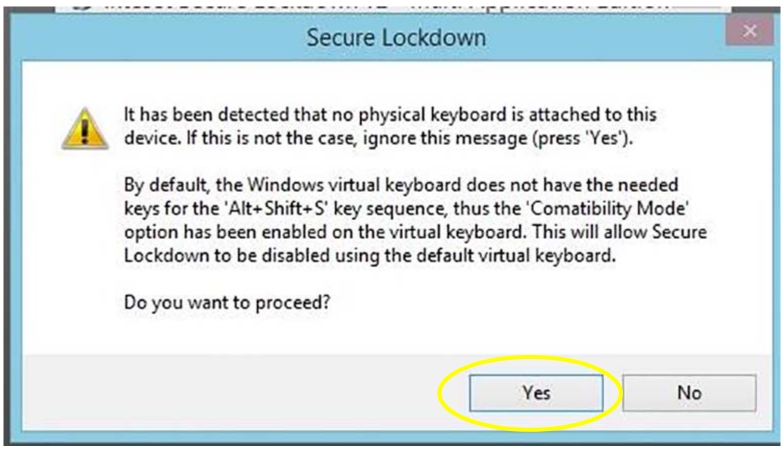
To enable Secure Lockdown again:

2. Simultaneously press “Alt, Shift and S” keys on the keyboard
3. Enter “s0t3r@9444” for the “Password”
4. Check the “Enable Secure Lockdown” box and Click “Apply”



A prompt indicating that “no physical keyboard is attached to the device...” will be displayed.

1. Click “Yes”



Next prompt will appear asking “Are you sure you want to enable Secure Lockdown”.

Re-activate Secure Lockdown

1. Click "Yes"

Last prompt will appear asking "Do you want to log out".

1. Click "No" to restart the computer and complete the process

Note: You must restart computer in order for changes to take effect.

- *Notes* -

Re-activate Secure Lockdown

Sotera WIRELESS

7. Troubleshooting

7.1 Introduction

Refer to the ViSi Mobile User Manual or contact Customer Service:

Toll-Free:	+1-866-232-6126
International:	+1-858-427-4620
Fax:	+1-999-2487
E-mail:	support@soterawireless.com

- Notes -

8. User/Preventative Maintenance

8.1 Introduction

This section of the manual outlines routine maintenance that should be performed by the user. The ViSi Mobile Monitoring System is designed for stable operation over long periods of time and, under normal circumstances, should not require technical maintenance beyond that described in this section.

8.2 Preventative Maintenance

All ViSi Mobile components are designed to internally calibrate each time they are used. Therefore, no routine calibration checks are required during routine preventative maintenance cycles. Routine testing of functionality/accuracy can be verified using standard electronic patient simulators and compared against the references in this manual.

Sotera Wireless, Inc. recommends preventative maintenance as follows:

Chest Sensor / Monitor	Visual inspections for mechanical abuse is recommended at a frequency consistent with use. Annual inspection is recommended but not required.
Cuff Module	Visual inspection and routine calibration checks against a known volume is recommended on an annual basis. The air filter should be replaced at this time. Calibration volume and replacement air filters can be purchased from Sotera Wireless, Inc. or the units can be returned to Sotera for a nominal fee.
SpO_2 Sensor	The SpO_2 sensor comes with a standard 3 month warranty. Actual life cycle duration is dependent on use and care. No preventative maintenance is required.
Optional ViSi Power Pack	Regular visual inspection for mechanical abuse is recommended at a frequency consistent with use. The ViSi Power Pack does not require calibration.

Note: Prior to any preventative or corrective service, ViSi Mobile components should be cleaned and disinfected. See below.

In the event any component needs to be returned to Sotera Wireless, Inc; contact the Sotera Wireless, Inc. Customer Service Department or the Sotera Wireless, Inc. representative in your area. Prior to shipping, ensure the returned components have been properly disinfected.

The ViSi Mobile Monitoring System components, including the ViSi Power Pack should only be serviced by Sotera Wireless, Inc. technicians or authorized service providers.

8.3 Cleaning and Disinfection

The ViSi Mobile Monitor, Cuff Module, Chest Sensor, Thumb Sensor, and Power Pack require cleaning and disinfection prior to reuse on a different patient. To prevent possible cross-contamination, properly clean and/or disinfect all ViSi Mobile reusable components between patients.

If the ViSi Power Pack beeper/buzzer sounds or the Red LED is permanently lit, the ViSi Power Pack should be disconnected from the patient immediately.

Do not clean the ViSi Mobile Monitor, Cuff Module, Chest Sensor, Thumb Sensor, or ViSi Power Pack with detergents while worn by the patient.

Do not clean the ViSi Mobile Monitor, the Cuff Module, or the Power Pack while it is plugged into the ViSi Mobile Charger.

Do not apply liquid to the ViSi Mobile Cuff Module or the Power Pack. To clean, use a damp cloth.

Ensure the sensor connector contacts are thoroughly dried to prevent possible malfunction.

Thumb sensors which are saturated with liquid should be allowed to air dry thoroughly before re-use.

Do not use bleach, abrasive cleaning agents or organic solvents on any of the ViSi Mobile Monitoring System components.

Use only recommended clenaing/disinfecting agents to prevent damage to the device and components. See page 107.

Do not autoclave the ViSi Mobile Monitor, its components, or accessories.

Do not use excessive amounts of liquid when cleaning the ViSi Mobile Chest Sensor or Thumb Sensor.

Prior to cleaning and disinfecting:

1. Pre-clean at the point of use to remove and prevent drying of soil and contaminants.
2. Ensure all components are disconnected, including the ViSi Mobile Monitor from the Wrist Cradle and the Thumb Sensor from the Thumb Wrap.
3. When cleaning the optional ViSi Power Pack, first remove the Power Pack from the Power Pack Cradle. All components of the ViSi Power Pack should be cleaned and disinfected between uses.

Recommended cleaning/disinfection agents. Use either of the following:

1. Clean with soap or detergent followed by disinfection with 70% isoprophyl alcohol.
2. Clean and disinfect with Super Sani-Cloth® Germicidal Disposable Wipes.

To clean the ViSi Mobile Monitoring System components

1. Hand-wash the System components using mild soap or detergent (e.g. Alconox) and water.

   Do not appy liqiud to the Cuff Module or Power Pack, instead use a damp cloth.
2. A soft-bristled brush may be used for heavily soiled areas, as needed.
3. Dry thoroughly using a soft cloth or paper towel.
4. Visually examine the reusable components to ensure all soil contaminants have been removed.
5. Repeat the above cleaning process as required.

Note: Use a new Super Sani-Cloth®; disinfect according to manufacturer's recommended procedure.

To disinfect the ViSi Mobile Monitoring System components

Do not use bleach, abrasive cleaning agents or organic solvents on any of the ViSi Mobile Monitoring System components.

Do not autoclave the ViSi Mobile Monitor, its components, or accessories.

Do not use excessive amounts of liquid when cleaning the ViSi Mobile Chest Sensor CableChest Sensor or the ViSi Mobile Thumb Sensor.

To disinfect the ViSi Mobile Monitoring System components:

1. Disinfect the reusable components by wiping with a Super Sani-Cloth® (purple top) or use a basic wipe moistened with ≤70% isopropyl alcohol.
2. Dry thoroughly using a soft cloth or paper towel.

Note: Use a new Super Sani-Cloth®; disinfect according to manufacturer's recommended procedure.

8.4 Inspecting Equipment and Accessories

After cleaning and disinfecting, you should visually inspect the ViSi Mobile Monitoring System components and replace any System components that show evidence of anomalies.

1. For each component, examine the exteriors for cleanliness and general physical conditions. Ensure the housings are not cracked or broken, that everything is present, there are no spilled liquids and no signs of abuse.
2. Inspect all component cables for damage. Check their strain relief (at flex points) for general condition. Ensure there are no breaks or cracks in the cables . If any cables show signs of damage, do not use.
3. Inspect all disposable accessories (Wrist Cradle, Cuff, Thumb Strap, Securements, etc). If any show signs of damage or pre-use, do not use.

8.4.1 ViSi Mobile Chest Sensor

The Chest Sensor measures ECG/Respiration Rate (impedance pneumography) and skin surface temperature. A standard patient simulator can be used to verify operation against the specifications found in this Manual. The temperature sensor can be checked by submersing the sensor in a heated water bath until the temperature sensor is submerged and comparing the ViSi displayed temperature against a calibrated thermometer. Allow time for the ViSi temperature sensor to equilibrate with the water bath for the time specified in the Temperature Specifications in this Manual.

8.4.2 ViSi Mobile SpO_2 Sensor

The functionality of the SpO_2 sensor can be verified using standard patient simulators. However, accuracy should NOT be determined from patient simulators since they cannot duplicate human physiology. The only way to determine accuracy is to compare the ViSi reading against a blood gas value. When troubleshooting in a clinical setting, first inspect the sensor for proper placement as shown in this User Manual.

8.4.3 ViSi Mobile Cuff Module

The functionality of the Cuff Module can be verified using a patient simulator capable of simulating oscillometric blood pressure during the cuff inflation cycle. Consult your NIBP patient simulator manual for information.

8.4.4 ViSi Mobile Charger

The charger initiates an internal calibration each time it is powered. In the case of an internal failure, the indicator light will NOT turn green under any condition. If such a condition occurs return the Charger to Sotera for service.

8.4.5 ViSi Mobile Remote Viewer/Appliance

Refer to hardware manuals provided at installation for functional verification. Software checks are provided remotely by Sotera Wireless, Inc. over a secure remote access (similar to a VPN) connection installed at the time of installation.

8.4.6 ViSi Mobile Monitoring System Battery Replacement

Within the ViSi Mobile Monitor, Cuff Module, and Power Pack, the battery is sealed. The battery technology is closely integrated with safety circuits and software to protect from hazardous and harmful conditions. The battery cannot be replaced with normal biomedical service tools. All battery service and replacement is performed by Sotera Wireless. Inc.

8.4.7 ViSi Mobile Optional Power Pack

Please see Appendix B -ViSi Power Pack on page 207

8.5 Product Disposal

To avoid contaminating or infecting personnel, the environment or other equipment, make sure to disinfect and decontaminate the ViSi Mobile Monitoring System, Thumb Sensor and disposables components appropriately before disposing of them in accordance with your country's laws for equipment containing electrical and electronic parts.

The ViSi Mobile Monitoring System components are designated for separate collection at an appropriate collection point. Do not dispose of as household waste. Refer to your facility's procedures.

After patient use, the disposables from the ViSi Disposable Kit may contain bio-hazard materials. Handle and dispose of these items according to your facility's policies.

Disposables from the ViSi Disposable Kit should be disposed of per your facility's procedures for bio-hazard materials.

Contact the Sotera Wireless, Inc. Customer Service Department or the Sotera Wireless, Inc. representative in your area to obtain additional information about cleaning and disinfecting the ViSi Mobile Monitoring System components or product disposal.

Product Disposal

Appendix A - Warranty

Warranty

Sotera Wireless, Inc. warrants to End User, for a period of one (1) year from the date of delivery, unless otherwise noted in specific documentation, that the products sold by Sotera Wireless, Inc. will operate in accordance with Sotera Wireless, Inc.'s published documentation in effect on the date of delivery or Sotera Wireless, Inc. will, at its sole discretion and expense, repair or replace the products. Replacements will be warranted for the remainder of the warranty period in effect on the original product purchased, unless otherwise mandated by applicable law. Products include Sotera Wireless, Inc. equipment only but does not include disposables / consumables. Sotera Wireless, Inc. warrants that its disposables / consumables products will be free from defects in workmanship and materials for a period of one (1) year from the date of purchase or the expiration date whichever occurs first.

Third Party Branded Products

Sotera Wireless, Inc. will not be deemed to provide, nor be responsible for, warranty, related remedy or support with respect to hardware, software or services purchased from a third party unless such party is a Sotera Wireless, Inc. authorized partner services Sotera Products and Services, unless otherwise agreed in writing between the parties.

Typically, in case of a defective 3rd party item under warranty, Sotera Wireless, Inc. will make arrangements with the 3rd party manufacturer to issue a replacement. The replacement will be sent directly to the End User site from the 3rd party manufacturer. No Return Material Authorization (RMA) will be issued by Sotera Wireless, Inc., instead a Sotera Case Number will be issued for the reported issue. The End User is responsible for complying with the manufacturer's replacement procedures.

Warranty Exclusions

Sotera Wireless, Inc. will not be liable under this warranty if its testing and/or examination discloses that the alleged defect in the Sotera Wireless, Inc. equipment does not exist or was caused by end user's or any unauthorized third person's misuse, neglect, improper installation or testing, attempts to repair, or any other cause beyond the scope of the intended use, or by accident, fire, lightning or other hazard or event of force majeure. The warranty for any hardware will become void if a hardware component is installed as an add-on and/or replacement part on the original hardware and such component part has not been approved for such inclusion by Sotera Wireless, Inc. The warranty for software will be voided if the software is modified, except as authorized in writing by Sotera Wireless, Inc.

In no event shall Sotera Wireless, Inc. be liable to end user or any third parties for any consequential, incidental, indirect, exemplary, punitive, contingent, statutory or any other special damages. Sotera Wireless, Inc.'s liability for damages on account of a claimed defect in any product delivered by Sotera Wireless, Inc. shall in no event exceed the purchase price of the product on which the claim is based. Specifically, and without limiting the generality of the foregoing, Sotera Wireless, Inc. shall not be responsible or liable to end user or any third party for any lost profits, or any consequential, incidental, punitive, contingent, statutory or any other special damages for any breach of warranty or other breach of Sotera Wireless, Inc.'s obligations under this agreement. Sotera Wireless, Inc. shall not be liable for damages relating to any instrument, equipment, or apparatus with which the product sold under this agreement is used. In addition, Sotera Wireless, Inc. disclaims all liability of any kind of Sotera Wireless, Inc.'s suppliers.

The foregoing warranties and remedies are exclusive and are in lieu of all other warranties, express or implied, either in fact or by operation of law, statutory or otherwise including warranties of merchantability and fitness for a particular purpose or non infringement.

Sotera Wireless, Inc. does not assume or authorize any other person to assume for it any other or greater liability in connection with the sale, installation, servicing, maintenance or use of Sotera Wireless, Inc. hardware, and Sotera Wireless, Inc. makes no warranty whatsoever with respect to any third-party branded products supplied by it hereunder.

Sotera Wireless, Inc. Responsibility

Sotera Wireless, Inc. is responsible for the effects on safety, reliability and performance of the equipment only if:

1. Assembly operations, extensions, readjustments, modifications or repairs are carried out by persons authorized by Sotera Wireless, Inc. and
2. The equipment is used in accordance with the instructions for use.

Contact Sotera Wireless

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EXHIBIT 3

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Attorneys for Plaintiff
MASIMO CORPORATION

IN THE UNITED STATES DISTRICT COURT

FOR THE SOUTHERN DISTRICT OF CALIFORNIA

MASIMO CORPORATION, a California corporation Plaintiff, v. SOTERA WIRELESS, a California corporation, HON HAI PRECISION INDUSTRY CO., LTD., a Taiwan corporation, Defendants.	Case No. '19CV1100 BAS NLS **COMPLAINT FOR PATENT INFRINGEMENT** **DEMAND FOR JURY TRIAL**

Plaintiff Masimo Corporation ("Masimo") hereby complains of Defendants Sotera Wireless, Inc. ("Sotera") and Hon Hai Precision Industry Co. Ltd. ("Foxconn") and alleges as follows:

I. THE PARTIES

1. Plaintiff Masimo is a Delaware corporation having its principal place of business at 52 Discovery, Irvine, California 92618.

2. Defendant Sotera is a California corporation having a principal place of business at 10020 Huennekens Street, San Diego, CA 92121. Sotera markets the ViSi Mobile Monitoring System, a monitoring platform and set of products intended to compete with Masimo's products.

3. Defendant Foxconn also known as Foxconn Technology Group, is a corporation organized and existing under the laws of Taiwan, with its principal place of business at No. 66, Zhongshan Road, Tucheng Industrial Zone, Tucheng Dist., New Taipei City, Taiwan, R.O.C. Foxconn is a multinational electronics manufacturing company. Foxconn owns an undisclosed stake in Sotera, and on information and belief, Foxconn controls Sotera and Sotera's management team.

II. JURISDICTION AND VENUE

4. This is a civil action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*., more particularly, 35 U.S.C. §§ 271 and 281.

5. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. Sotera resides in California and is subject to personal jurisdiction in California, and, on information and belief, has committed the acts complained of in this Judicial District.

7. Foxconn resides in Taiwan and is subject to specific and general personal jurisdiction in California due to Foxconn's substantial business in

California. For example, Foxconn maintains a branch office at 105 S. Puente Street, Brea, California 92821. Furthermore, Foxconn has filed suit in this judicial district. On information and belief, Foxconn has transacted business in this judicial district and committed acts within this judicial district giving rise to this action, directly and/or through subsidiaries, agents and partners.

8. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1400(b) as to Sotera because Sotera has its regular and established place of business in the County of San Diego within the Southern District of California.

9. Venue is proper in this Judicial District pursuant to 28 U.S.C. § 1391(c)(3) as to Foxconn.

III. MASIMO'S INNOVATIVE TECHNOLOGY

10. Masimo is a medical technology company that revolutionized pulse oximetry and is the only company to have succeeded in developing noninvasive patient monitoring technologies for hemoglobin, methemoglobin, and carboxyhemoglobin. Pulse oximetry is a noninvasive method for monitoring a person's arterial oxygen saturation (also called "SpO_2") and pulse rate from a sensor that is attached to a user. Before Masimo, pulse oximetry was plagued by unreliability, often when the measurement was needed most, due to patient motion and low peripheral blood flow (known as "low perfusion"). The industry had essentially given up on solving this problem, concluding it was largely unsolvable. Clinicians had to live with the results – patient monitors gave excessive false alarms, froze their measurements for prolonged periods of time despite potential changes in oxygen saturation or pulse rate, delayed notification of alarms due to long averaging times of sensor data, produced inaccurate measurements, or were unable to obtain data on the most critical patients and babies who cannot be instructed to stay still. Masimo's pioneering technology, known as Masimo Signal Extraction Technology ("Masimo SET"), solved this problem and dramatically improved patient safety by accurately

monitoring and reporting oxygen saturation and pulse rate even during motion and low perfusion.

11. Following its success in pulse oximetry, Masimo subsequently invested in developing additional breakthrough measurement technologies, such as non-invasively measuring total hemoglobin, methemoglobin, and carboxyhemoglobin. Masimo has continued to innovate, succeeding where others have consistently failed. Masimo was the first, and remains the only, company delivering these game-changing technologies to hospitals in the United States.

12. With measurement innovation at its core, Masimo helped clinicians benefit from continuous monitoring of key physiologic measurements and intuitive centralized displays of real-time patient data. Masimo applied the power of its breakthrough measurements to patient-worn monitors designed to allow patient mobility and continuous monitoring. Masimo's small wearable monitors allow untether monitoring that promote greater patient comfort and independence. Masimo also developed monitors with wireless communications technologies to further advance continuous monitoring. These advances also reduce the need for nurses to disconnect a monitor each time a patient gets out of bed.

13. To benefit clinicians and patients in comprehending Masimo's gold-standard data, Masimo developed intuitive displays of real-time patient data. Masimo's contributions include specific techniques for presenting large amounts of data in a quickly comprehensible manner. Using color, animation, arrangement, and organization, Masimo's technologies allow clinicians to rapidly assess patient status. When paired with the reduction in false alarms and overall accuracy of Masimo's technologies, these visual interfaces allow for efficient monitoring of patient status and improve patient care.

14. Masimo's technologies also include Masimo's pioneering Patient SafetyNet System ("Masimo Patient SafetyNet"), which improves patient safety by providing remote monitoring and clinician notification of patient data such as continuous pulse oximetry, heart rate, blood pressure, electrocardiogram, and ventilation monitoring. Masimo Patient SafetyNet combines the gold-standard performance of Masimo's monitoring technologies with information collected from any connected Masimo or third-party patient device to provide alarms, alerts and near-real time information to be sent to remote locations, for example, directly to clinicians. The system allows clinicians to monitor multiple patients simultaneously and to automatically transfer data from medical devices to electronic medical records. Masimo's innovation in that space continue to drive medical monitoring technologies and improve patient outcomes.

15. From its inception, Masimo has continuously developed cutting-edge, noninvasive patient monitoring technologies. Masimo sought and received numerous U.S. patents for many of its inventions in these areas. Masimo's revolutionary technology was a key to its gaining significant market praise and penetration. After introduction into the market, many competitors, much larger than Masimo, used Masimo's technology without a license, resulting in patent infringement lawsuits that resulted in jury verdicts of infringement, damages, and confirmation of the validity of Masimo's innovations.

IV. <u>THE PATENTS-IN-SUIT</u>

16. Masimo is the owner by assignment of U.S. Patent No. 9,788,735 entitled "Body Worn Mobile Medical Patient Monitor" ("the '735 patent"), which the United States Patent and Trademark Office lawfully and duly issued on October 17, 2017. A true and correct copy of the '735 patent is attached hereto as Exhibit 1.

17. Masimo is the owner by assignment of U.S. Patent No. 9,795,300 entitled "Wearable Portable Patient Monitor" ("the '300 patent"), which the United States Patent and Trademark Office lawfully and duly issued on October 24, 2017. A true and correct copy of the '300 patent is attached hereto as Exhibit 2.

18. Masimo is the owner by assignment of U.S. Patent No. 9,872,623 entitled "Arm Mountable Portable Patient Monitor" ("the '623 patent"), which the United States Patent and Trademark Office lawfully and duly issued on January 23, 2018. A true and correct copy of the '623 patent is attached hereto as Exhibit 3.

19. Masimo is the owner by assignment of U.S. Reissue Patent No. RE47,218 entitled "Adaptive Alarm System" ("the RE218 patent"), which the United States Patent and Trademark Office lawfully and duly issued on February 5, 2019. A true and correct copy of the RE218 patent is attached hereto as Exhibit 4.

20. Masimo is the owner by assignment of U.S. Reissue Patent No. RE47,244 entitled "Alarm Suspend System" ("the RE244 patent"), which the United States Patent and Trademark Office lawfully and duly issued on February 19, 2019. A true and correct copy of the RE244 patent is attached hereto as Exhibit 5.

21. Masimo is the owner by assignment of U.S. Reissue Patent No. RE47,249 entitled "Alarm Suspend System" ("the RE249 patent"), which the United States Patent and Trademark Office lawfully and duly issued on February 19, 2019. A true and correct copy of the RE249 patent is attached hereto as Exhibit 6.

22. Masimo is the owner by assignment of U.S. Patent No. 10,213,108 entitled "Arm Mountable Portable Patient Monitor" ("the '108 patent"), which the United States Patent and Trademark Office lawfully and duly issued on

February 26, 2019. A true and correct copy of the ’108 patent is attached hereto as Exhibit 7.

23. Masimo is the owner by assignment of U.S. Patent No. 10,255,994 entitled “Physiological Parameter Alarm Delay” (“the ’994 patent”), which the United States Patent and Trademark Office lawfully and duly issued on April 9, 2019. A true and correct copy of the ’994 patent is attached hereto as Exhibit 8.

24. Masimo is the owner by assignment of U.S. Reissue Patent No. RE47353 entitled “Alarm Suspend System” (“the RE47353 patent”), which the United States Patent and Trademark Office lawfully and duly issued on April 16, 2019. A true and correct copy of the RE353 patent is attached hereto as Exhibit 9.

V. <u>DEFENDANTS’ ACTIVITIES</u>

25. Sotera has made, used, offered to sell, and/or sold within the United States, and/or has imported into the United States, products including at least Sotera’s ViSi Mobile Monitoring System, a platform for vital signs monitoring, including pulse oximetry, pulse rate, and respiration rate. The ViSi Mobile Monitoring System includes a ViSi Mobile Monitor, ViSi Mobile Thumb Sensor, ViSi Mobile Cuff Module, ViSi Mobile Chest Sensor Cable, ViSi Mobile Wrist Strap, and ViSi Mobile Wrist Cradle. A picture of the ViSi Mobile Monitoring System from the product’s User Manual is reproduced below:

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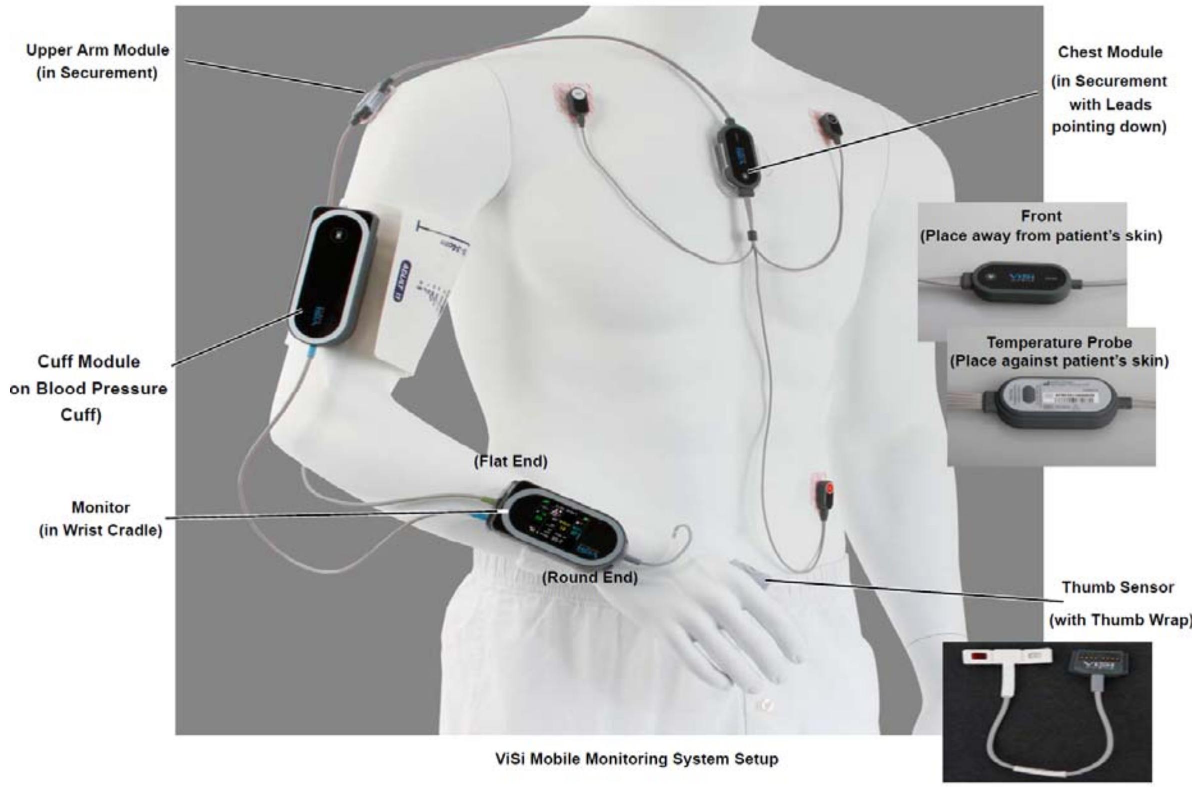

ViSi Mobile Monitoring System Setup

26. On information and belief, Foxconn has directly or indirectly controlled activities by Sotera including making, using, offering to sell, and/or selling within the United States, and/or importing into the United States, products including at least Sotera's ViSi Mobile Monitoring System. Foxconn has announced plans to make Sotera's ViSi Mobile Monitoring components and products, including at least batteries and sensors for the products.

VI. <u>CLAIMS FOR PATENT INFRINGEMENT</u>

VII. <u>FIRST CLAIM FOR RELIEF</u>

<u>(Infringement of U.S. Patent No. 9,788,735)</u>

27. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 26.

28. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claim 20 of the '735 patent under at least 35 U.S.C. § 271(a), (b), and (c).

29. Upon information and belief, Sotera has directly infringed one or more claims of the ’735 patent through manufacture use, sale, offer for sale, and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.

30. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera’s customers to infringe one or more claims of the ’735 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.

31. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 20 of the ’735 patent. The ViSi Mobile is a body worn portable patient monitoring device configured to provide on-patient and remote monitoring of patient physiological parameters, the portable patient monitoring device. The ViSi Mobile includes a pulse oximetry sensor configured to be wrapped around a digit of a patient, the patient’s thumb. The ViSi Mobile pulse oximetry sensor includes a light emitter configured to emit light into a tissue site of the patient’s thumb. The ViSi Mobile pulse oximetry sensor also includes a light detector configured output a first signal. That first signal is responsive to at least a portion of the emitted light after attenuation by tissue on the patient’s thumb. ViSi Mobile pulse oximetry sensor also includes a cable extending from the pulse oximetry sensor and configured to electrically convey the first signal. The ViSi Mobile further includes a blood pressure sensor configured to output a second signal responsive to at least a blood pressure parameter of the patient. The ViSi Mobile also includes an additional sensor arrangement, the ViSi Mobile chest sensor, configured to output a third signal responsive to an additional physiological parameter of the patient, temperature or respiration rate. The ViSi Mobile also

has a housing configured to be secured to a lower arm of the patient, the housing having a size and shape configured to be secured to the lower arm of the patient. The ViSi Mobile also has a strap mountable to the back side of the housing, the strap configured to secure the housing to the lower arm of the patient. The ViSi Mobile includes a display positioned on a front side of the housing that is opposite a back side of the housing. The ViSi Mobile display is configured to show the status of the ViSi Mobile and multiple parameter measurements, such as SpO_2 and blood pressure, so as to be viewable by a user. The ViSi Mobile display is positioned centrally on the front side of the ViSi Mobile and is sized such that the display spans most of a length of a shortest dimension of the front side of the housing. The front side of the ViSi Mobile housing comprises a single user interface and a bezel. The ViSi Mobile also includes one or more user input mechanisms, such as the touch screen of the device, configured to control an operational mode of the ViSi Mobile in response to inputs from a user. The ViSi Mobile also includes a first sensor port positioned on a face of a first side of the housing. The face of the first side of the housing of the ViSi Mobile is configured to face toward a hand having the digit of the patient under measurement when the housing is secured to the lower arm of the patient. The first sensor port of the ViSi Mobile is configured to removably physically couple with the ViSi Mobile thumb pulse oximetry sensor via the cable and to electrically receive the first signal from the pulse oximetry sensor. The cable of the thumb sensor of the ViSi Mobile is configured to run from the first sensor port, at least part way along a path substantially perpendicular to the face of the first side of the housing, down the arm of the patient, and to the digit of the patient, the thumb, to which the pulse oximetry sensor is configured to be wrapped around. The front side of the housing of the ViSi Mobile is raised from the strap and the lower arm of the patient to enable positioning of the first sensor port on the first side of the housing between the lower arm of the patient and the

front side of the housing. The top of the first sensor port of the ViSi Mobile is located below the front of the housing. The ViSi Mobile also includes a second sensor port positioned on the housing and configured to provide wired electrical communication with the ViSi Mobile blood pressure sensor arrangement. The ViSi Mobile second sensor port electrically receives a second signal from the blood pressure sensor arrangement. The ViSi Mobile also includes a third sensor port positioned on the housing and configured to provide electrical wired communication with the ViSi Mobile ECG sensor arrangement and electrically receives the third signal from the additional sensor arrangement. The ViSi Mobile also includes a rechargeable battery positioned within the housing and configured to power the portable patient monitoring device such that the portable patient monitoring device is portable and wearable by the patient. The ViSi Mobile further includes one or more signal processing arrangements positioned within the housing. The ViSi Mobile signal processors receive the first signal from the pulse oximetry sensor via one or more sensor interfaces, that first signal is provided at least partly as an analog signal. The ViSi Mobile signal processor process the first signal from the pulse oximetry sensor to determine measurements of oxygen saturation and pulse rate. The signal processor also receives the second signal from the blood pressure sensor arrangement via the one or more sensor interfaces, the second signal responsive to at least a blood pressure parameter of the patient. The ViSi mobile signal processor also receives the third signal from the additional sensor arrangement via the one or more sensor interfaces, the third signal responsive to the at least temperature or respiration rate of the patient. That third signal is provided at least partly as a digital signal. The ViSi Mobile also causes the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter, temperature or ECG from the chest sensor, to all be displayed on the ViSi Mobile display. and a The ViSi Mobile includes an

802.11b transmitter positioned within the housing and configured to: wirelessly transmit a transmit signal including the information indicating the measurements of oxygen saturation, pulse rate, blood pressure, and the temperature or respiration rate to a separate computing device, such as the ViSi Remote Viewer. The ViSi Remote viewer is configured to display, on its remote display, the measurements of oxygen saturation, pulse rate, blood pressure, and temperature or respiration rate.

32. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the '735 patent by hiring former Masimo employees and after previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the '735 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the '735 patent no later than the filing of this Complaint.

33. Upon information and belief, Sotera and Foxconn actively induce others to infringe the '735 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the '735 patent. To that end, Sotera provides instructions and teachings to customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the '735 patent. Sotera's acts and Foxconn's acts constitute infringement of the '735 patent in violation of 35 U.S.C. § 271(b).

34. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of the '735 patent. By way of example only, upon information and belief, Sotera and Foxconn actively induce direct infringement of the '735 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other

materials necessary for the use, refurbishing, and/or servicing of the ViSi Mobile Monitor. Upon information and belief, Sotera and Foxconn knew or should have known that these activities would cause direct infringement.

35. Upon information and belief, Sotera's acts and Foxconn's acts constitute contributory infringement of the '735 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, Sotera and Foxconn contributorily infringe because, among other things, Sotera offers to sell and/or sells within the United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the '735 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the '735 patent.

36. Upon information and belief, Sotera's infringement of the '735 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '735 patent and its infringement thereof, thus acting in reckless disregard of Masimo's patent rights.

37. As a consequence of Sotera's and Foxconn's infringement of the '735 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

38. Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

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VIII. SECOND CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 9,795,300)

39. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 38.

40. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claims 16-20 of the ’300 patent under at least 35 U.S.C. § 271(a), (b), and (c).

41. Upon information and belief, Sotera has directly infringed one or more claims of the ’300 patent through manufacture use, sale, offer for sale, and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.

42. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera’s customers to infringe one or more claims of the ’300 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.

43. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 16 of the ’300 patent. The ViSi Mobile is a battery-powered wearable physiological monitoring device configured to communicate with multiple types of sensor arrangements via a plurality of sensor interfaces. The ViSi Mobile has three sensor communication ports including: a first sensor communication port configured to provide wired communication with a first type of physiological sensor arrangement, a ViSi Mobile thumb pulse oximetry sensor. The first sensor port of the ViSi Mobile is positioned on the device such that a wire extending from the first sensor communication port to the first type of physiological sensor arrangement extends from the device along an axis perpendicular to a face of the device upon

which the first sensor port is positioned. The ViSi Mobile also includes a second sensor communication port configured to provide wired communication with a second type of physiological sensor arrangement, a ViSi Mobile blood pressure sensor. The blood pressure sensor is different from pulse oximetry sensor. The ViSi Mobile also includes a third sensor communication port configured to provide wired communication with a third type of physiological sensor arrangement, an ECG. The ECG different from both the pulse oximetry and blood pressure sensor arrangements. The ViSi Mobile includes a plurality of sensor interfaces including a first sensor interface configured to receive a first signal from a pulse oximetry sensor. The first signal includes analog information. The ViSi Mobile includes a second sensor interface configured to receive a second signal from a blood pressure sensor, the second signal including digital information. The ViSi Mobile further includes a third sensor interface, the ECG interface, configured to receive a third signal from an ECG sensor arrangement. The plurality of sensor interfaces in the ViSi Mobile are configured to output one or more signals indicative of physiological parameters sensed by the first, second, and third sensor arrangements. The ViSi Mobile further includes a display positioned on its face configured to display information while the wearable physiological monitoring device is being worn by a patient. The ViSi Mobile also includes a processor configured to be responsive to the one or more signals indicative of the physiological parameters, and cause to be displayed, on the display, physiological parameter measurements. The ViSi Mobile combines information indicative of the one or more signals into a single digital word or bit stream for transmission over 802.11b. The ViSi Mobile encodes the single digital word or bit stream to generate a baseband signal for 802.11b. The ViSi Mobile also includes a transmitter configured to: modulate the baseband signal with a carrier to generate a transmit signal. In operation, the ViSi Mobile wirelessly transmits

the transmit signal to a receiving patient monitoring device that is not wired to the wearable physiological monitoring device. The ViSi Mobile also includes a single cell Li-ION battery configured to provide power to at least the processor, the display, the transmitter, and the first sensor arrangement via the first sensor communication port such that the wearable physiological monitoring device is portable and wearable by a patient.

44. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the '300 patent by hiring former Masimo employees and following previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the '300 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the '300 patent no later than the filing of this Complaint.

45. Upon information and belief, Sotera and Foxconn actively induce others to infringe the '300 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the '300 patent. To that end, Sotera provides instructions and teachings to its customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the '300 patent. Sotera's acts and Foxconn's acts constitute infringement of the '300 patent in violation of 35 U.S.C. § 271(b).

46. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of the '300 patent. By way of example only, upon information and belief, Sotera and Foxconn actively induce direct infringement of the '300 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the ViSi

Mobile Monitor. Upon information and belief, Sotera and Foxconn knew or should have known that these activities would cause direct infringement.

47. Upon information and belief, Sotera's acts and Foxconn's acts constitute contributory infringement of the '300 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, Sotera and Foxconn contributorily infringe because, among other things, Sotera offers to sell and/or sells within the United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the '300 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the '300 patent.

48. Upon information and belief, Sotera's and Foxconn's infringement of the '300 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '300 patent and its infringement thereof, thus acting in reckless disregard of Masimo's patent rights.

49. As a consequence of Sotera's and Foxconn's infringement of the '300 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

50. Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

THIRD CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 9,872,623)

51. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 50.

52. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claims 1-16 of the ’623 patent under at least 35 U.S.C. § 271(a), (b), and (c).

53. Upon information and belief, Sotera has directly infringed one or more claims of the ’623 patent through manufacture use, sale, offer for sale, and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.

54. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera’s customers to infringe one or more claims of the ’623 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.

55. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 1 of the ’623 patent. The ViSi Mobile Monitor is an arm mountable portable patient monitoring device configured for both on-patient monitoring of parameter measurements using one or more sensors operatively connected to the portable patient monitoring device and wireless transmission of parameter measurements. The ViSi Mobile Monitor includes a pulse oximetry sensor at its thumb sensor configured to be wrapped around a digit of a patient. The pulse oximetry sensor of the ViSi Mobile Monitor includes a light emitter configured to emit light into a tissue site of the digit of the patient; a light detector configured output a signal responsive to at least a portion of the emitted light after attenuation by tissue of the tissue site; and a tail configured to electrically convey the signal. The ViSi Mobile Monitor includes a housing configured for, and having a size and shape configured for, mounting to a lower arm of the patient. The ViSi Mobile Monitor includes a display positioned on a front side of the housing that is

opposite a back side of the housing. The display of the ViSi Mobile Monitor is configured to show a status of the portable patient monitoring device and one or more parameter measurements so as to be viewable by a user. The ViSi Mobile Monitor includes a first sensor port positioned on a first side of the housing and the first side of the housing is configured to face toward a hand having the digit of the patient under measurement. The first sensor port of the ViSi Mobile Monitor is configured to physically couple to the tail of the pulse oximetry sensor and to electrically receive the signal from the pulse oximetry sensor. The first sensor port of the ViSi Mobile Monitor is positioned on the first side of the housing such that, when the tail is physically coupled to the first sensor port, the tail extends from the first sensor port along an axis perpendicular to a face of the first side of the housing on which the first sensor port is positioned. The ViSi Mobile Monitor also includes a second sensor port configured to receive information from an EKG sensor arrangement via a wired connection and a third sensor port configured to receive information from a blood pressure sensor arrangement via a wired connection. The ViSi Mobile Monitor includes a Li-Ion rechargeable battery configured to power the ViSi Mobile Monitor including the pulse oximetry sensor. The ViSi Mobile Monitor includes one or more signal processing arrangements configured to receive the signal from the pulse oximetry sensor; derive, based on the signal, measurements of oxygen saturation and pulse rate; and cause to be displayed, on the display, the measurements of oxygen saturation and pulse rate. The ViSi Mobile Monitor includes a transmitter configured to wirelessly transmit a transmit signal indicative of the measurements of oxygen saturation and pulse rate to a separate computing device configured to display the measurements of oxygen saturation and pulse rate. The ViSi Mobile Monitor includes a wrist strap mountable to the back side of the housing. The wrist strap of the ViSi Mobile Monitor is configured to secure the housing to the lower arm of the patient.

56. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the '623 patent by hiring former Masimo employees and following previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the '623 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the '623 patent no later than the filing of this Complaint.

57. Upon information and belief, Sotera and Foxconn have actively induced others to infringe the '623 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the '623 patent. To that end, Sotera provides instructions and teachings to its customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the '623 patent. Sotera's acts and Foxconn's acts constitute infringement of the '623 patent in violation of 35 U.S.C. § 271(b).

58. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of the '623 patent. By way of example only, upon information and belief, Sotera actively induces direct infringement of the '623 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the ViSi Mobile Monitor. Upon information and belief, Sotera knew or should have known that these activities would cause direct infringement.

59. Upon information and belief, Sotera's acts and Foxconn's acts constitute contributory infringement of the '623 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, Sotera and Foxconn contributorily infringe because, among other things, Sotera offers to sell and/or sells within the

United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the ’623 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the ’623 patent.

60. Upon information and belief, Sotera’s and Foxconn’s infringement of the ’623 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the ’623 patent and its infringement thereof, thus acting in reckless disregard of Masimo’s patent rights.

61. As a consequence of Sotera’s and Foxconn’s infringement of the ’623 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

62. Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

FOURTH CLAIM FOR RELIEF

(Infringement of U.S. Reissue Patent No. RE47,218)

63. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 62.

64. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claims 1-10, and 12-18 of the RE218 patent under at least 35 U.S.C. § 271(a), (b), and (c).

65. Upon information and belief, Sotera has directly infringed one or more claims of the RE218 patent through manufacture use, sale, offer for sale,

and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.

66. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera's customers to infringe one or more claims of the RE218 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.

67. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 1 of the RE218 patent. The ViSi Mobile Monitoring System is a system for reducing electronic alarms in a medical patient monitoring system. The ViSi Mobile Monitoring System includes a ViSi Mobile Monitor having an optical sensor at its thumb sensor configured to transmit optical radiation into a tissue site of a patient and detect attenuated optical radiation indicative of at least one physiological parameter of a patient. The ViSi Mobile Monitor includes one or more hardware processors in electronic communication with the optical sensor. The one or more hardware processors of the ViSi Mobile Monitor is configured to determine oxygen saturation values of the patient over a first period of time and, when at least one oxygen saturation value obtained over the first period of time exceeds a first alarm threshold, determine whether a first alarm should be triggered. The one or more hardware processors of the ViSi Mobile Monitor is configured to access a second alarm threshold to be applied during a second period of time subsequent to the first period of time. The second alarm threshold replaces the first alarm threshold, and the second alarm threshold has a value less than the at least one oxygen saturation value and greater than a lower limit and at an offset from the at least one oxygen saturation value. The offset is diminished as a difference between the at least first oxygen saturation value and

the lower limit diminishes. The one or more hardware processors of the ViSi Mobile Monitor is also configured to determine oxygen saturation values of the patient over the second period of time and trigger a second alarm based on at least one value of the oxygen saturation values obtained over the second period of time exceeding the second alarm threshold.

68. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the RE218 patent by hiring former Masimo employees and after previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the RE218 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the RE218 patent no later than the filing of this Complaint.

69. Upon information and belief, Sotera and Foxconn have actively induced others to infringe the RE218 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the RE218 patent. To that end, Sotera provides instructions and teachings to its customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the RE218 patent. Sotera's acts and Foxconn's acts constitute infringement of the RE218 patent in violation of 35 U.S.C. § 271(b).

70. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of the RE218 patent. By way of example only, upon information and belief, Sotera actively induces direct infringement of the RE218 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the ViSi

Mobile Monitor. Upon information and belief, Sotera and Foxconn knew or should have known that these activities would cause direct infringement.

71. Upon information and belief, Sotera's acts and Foxconn's acts constitute contributory infringement of the RE218 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, Sotera and Foxconn contributorily infringe because, among other things, Sotera offers to sell and/or sells within the United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the RE218 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the RE218 patent.

72. Upon information and belief, Sotera's and Foxconn's infringement of the RE218 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the RE218 patent and its infringement thereof, thus acting in reckless disregard of Masimo's patent rights.

73. As a consequence of Sotera's and Foxconn's infringement of the RE218 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

74. Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

FIFTH CLAIM FOR RELIEF

(Infringement of U.S. Reissue Patent No. RE47,244)

75. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 74.

76. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claims 1-2, 6, 8, 9, 13-15, 18-26 of the RE244 patent under at least 35 U.S.C. § 271(a), (b), and (c).

77. Upon information and belief, Sotera has directly infringed one or more claims of the RE244 patent through manufacture use, sale, offer for sale, and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.

78. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera's customers to infringe one or more claims of the RE244 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.

79. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 1 of the RE244 patent. The ViSi Mobile Monitoring System is a physiological measurement system including a ViSi Mobile Monitor. The ViSi Mobile Monitor includes a noninvasive physiological sensor at its thumb sensor configured to be positioned on a patient and output a signal responsive to a physiological condition of the patient. The ViSi Mobile Monitor includes one or more processors in communication with the noninvasive physiological sensor. The one or more processors of the ViSi Mobile Monitor is configured to electronically process the signal; responsive to processing the signal, determine a measurement of a physiological parameter based at least in part upon the signal; and determine that the measurement of the physiological parameter satisfies an alarm activation threshold. The one or more processors of the ViSi Mobile Monitor is also configured to electronically initiate a parameter-specific alarm delay or suspension period of time corresponding to the physiological parameter. The

parameter-specific alarm delay or suspension period of time is one of a plurality of parameter-specific alarm delay or suspension periods of time, and the parameter-specific alarm delay or suspension period of time is different from at least one other parameter-specific alarm delay or suspension period of time corresponding to at least one other physiological parameter for which the one or more processors are configured to determine at least one measurement. The one or more processors of the ViSi Mobile Monitor is configured to electronically activate an alarm for the physiological parameter in response to expiration of an amount of delay or suspension associated with the parameter-specific alarm delay or suspension period of time.

80. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the RE244 patent by hiring former Masimo employees and after previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the RE244 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the RE244 patent no later than the filing of this Complaint.

81. Upon information and belief, Sotera and Foxconn have actively induced others to infringe the RE244 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the RE244 patent. To that end, Sotera provides instructions and teachings to its customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the RE244 patent. Sotera's acts and Foxconn's acts constitute infringement of the RE244 patent in violation of 35 U.S.C. § 271(b).

82. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of

the RE244 patent. By way of example only, upon information and belief, Sotera actively induces direct infringement of the RE244 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the ViSi Mobile Monitor. Upon information and belief, Sotera and Foxconn knew or should have known that these activities would cause direct infringement.

83. Upon information and belief, Sotera's acts and Foxconn's acts constitute contributory infringement of the RE244 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, Sotera and Foxconn contributorily infringe because, among other things, Sotera offers to sell and/or sells within the United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the RE244 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the RE244 patent.

84. Upon information and belief, Sotera's and Foxconn's infringement of the RE244 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the RE244 patent and its infringement thereof, thus acting in reckless disregard of Masimo's patent rights.

85. As a consequence of Sotera's and Foxconn's infringement of the RE244 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

86. Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

SIXTH CLAIM FOR RELIEF

(Infringement of U.S. Reissue Patent No. RE47,249)

87. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 86.

88. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claims 1-2, 6-9, 13-15, and 18-24 of the RE249 patent under at least 35 U.S.C. § 271(a), (b), and (c).

89. Upon information and belief, Sotera has directly infringed one or more claims of the RE249 patent through manufacture use, sale, offer for sale, and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.

90. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera's customers to infringe one or more claims of the RE249 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.

91. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 1 of the RE249 patent. The ViSi Mobile Monitoring System is a physiological measurement system including a ViSi Mobile Monitor. The ViSi Mobile Monitor includes a noninvasive physiological sensor at its thumb sensor configured to be positioned on a patient and output a signal responsive to a physiological condition of the patient. The ViSi Mobile Monitor includes one or more processors in communication with the noninvasive physiological sensor. The one or more processors of the ViSi Mobile Monitor is configured to electronically determine a measurement of a physiological parameter based at least in part upon the

signal, and determine whether an alarm condition exists by determining whether an activation threshold has been satisfied by the measurement of the physiological parameter. The one or more processors of the ViSi Mobile Monitor is also configured to electronically access an alarm hold initiator for a parameter-specific alarm hold period of time corresponding to the physiological parameter. The parameter-specific alarm hold period of time is one of a plurality of parameter-specific alarm hold periods of time, and the parameter-specific alarm hold period of time is different from at least one other parameter-specific alarm hold period of time corresponding to at least one other physiological parameter for which the one or more processors are configured to determine at least one measurement. The one or more processors of the ViSi Mobile Monitor is configured to electronically determine that the alarm hold initiator indicates to hold an indication of an alarm for the alarm condition and, in response to determining that the alarm hold initiator indicates to hold the indication of the alarm, hold the indication of the alarm for the parameter-specific alarm hold period of time. The one or more processors of the ViSi Mobile Monitor is configured to electronically, subsequent to the parameter-specific alarm hold period of time passing, activate the indication of the alarm while the measurement of the physiological parameter satisfies the activation threshold.

92. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the RE249 patent by hiring former Masimo employees and after previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the RE249 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the RE249 patent no later than the filing of this Complaint.

93. Upon information and belief, Sotera and Foxconn have actively induced others to infringe the RE249 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the RE249 patent. To that end, Sotera provides instructions and teachings to its customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the RE249 patent. Sotera's acts and Foxconn's acts constitute infringement of the RE249 patent in violation of 35 U.S.C. § 271(b).

94. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of the RE249 patent. By way of example only, upon information and belief, Sotera actively induces direct infringement of the RE249 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the ViSi Mobile Monitor. Upon information and belief, Sotera and Foxconn knew or should have known that these activities would cause direct infringement.

95. Upon information and belief, Sotera's acts and Foxconn's acts constitute contributory infringement of the RE249 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, Sotera and Foxconn contributorily infringe because, among other things, Sotera offers to sell and/or sells within the United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the RE249 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the RE249 patent.

96. Upon information and belief, Sotera's and Foxconn's infringement of the RE249 patent has been, and continues to be, willful, deliberate, and

intentional by continuing its acts of infringement after becoming aware of the RE249 patent and its infringement thereof, thus acting in reckless disregard of Masimo's patent rights.

97. As a consequence of Sotera's and Foxconn's infringement of the RE249 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

98. Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

SEVENTH CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 10,213,108)

99. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 98.

100. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claims 1-22 of the '108 patent under at least 35 U.S.C. § 271(a), (b), and (c).

101. Upon information and belief, Sotera has directly infringed one or more claims of the '108 patent through manufacture use, sale, offer for sale, and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.

102. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera's customers to infringe one or more claims of the '108 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.

103. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 1 of the ’108 patent. The ViSi Mobile Monitor is an arm mountable portable patient monitoring device configured to receive physiological information from a plurality of sensors attached to a patient at least two different measurement sites via wired connections for on-patient monitoring of parameter measurements and wireless transmission of parameter measurements to separate monitoring devices. The ViSi Mobile Monitor includes a housing configured to be secured to an arm of a patient under measurement. The ViSi Mobile Monitor includes a wrist strap mountable to a back side of the housing and configured to secure the housing to the arm of the patient. The ViSi Mobile Monitor includes a display positioned on a front side of the housing. The display of the ViSi Mobile Monitor is configured to show at least one status indicator of the portable patient monitoring device and one or more parameter measurements. The ViSi Mobile Monitor includes a first sensor port positioned on a first side of the housing and the first side of the housing is configured to face toward a hand of the arm of the patient when the housing is secured to the arm of the patient. The first sensor port of the ViSi Mobile Monitor is configured to electrically receive a signal from a thumb-type pulse oximetry sensor via a wired connection from the pulse oximetry sensor to the first sensor port. The wired connection is configured to extend from the first sensor port along a path substantially perpendicular to the first side of the housing. The ViSi Mobile Monitor also includes a second sensor port positioned on the housing and configured to receive a signal from a second sensor arrangement via a wired connection, and a third sensor port positioned on the housing configured to receive a signal from a third sensor arrangement via a wired connection. The ViSi Mobile Monitor includes one or more signal processing arrangements configured to receive the signal from the pulse oximetry sensor and cause to be displayed, on the display, at least

measurements of oxygen saturation and pulse rate derived from the signal. The ViSi Mobile Monitor includes a transmitter configured to wirelessly transmit information indicative of the measurements of oxygen saturation and pulse rate to a separate monitoring device configured to receive the information indicative of the measurements of oxygen saturation and pulse rate.

104. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the '108 patent by hiring former Masimo employees and after previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the '108 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the '108 patent no later than the filing of this Complaint.

105. Upon information and belief, Sotera and Foxconn have actively induced others to infringe the '108 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the '108 patent. To that end, Sotera provides instructions and teachings to its customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the '108 patent. Sotera's acts and Foxconn's acts constitute infringement of the '108 patent in violation of 35 U.S.C. § 271(b).

106. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of the '108 patent. By way of example only, upon information and belief, Sotera actively induces direct infringement of the '108 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the ViSi Mobile Monitor.

Upon information and belief, Sotera and Foxconn knew or should have known that these activities would cause direct infringement.

107. Upon information and belief, Sotera's acts and Foxconn's acts constitute contributory infringement of the '108 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, Sotera and Foxconn contributorily infringe because, among other things, Sotera offers to sell and/or sells within the United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the '108 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the '108 patent.

108. Upon information and belief, Sotera's and Foxconn's infringement of the '108 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the '108 patent and its infringement thereof, thus acting in reckless disregard of Masimo's patent rights.

109. As a consequence of Sotera's and Foxconn's infringement of the '108 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

110. Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

EIGHTH CLAIM FOR RELIEF

(Infringement of U.S. Patent No. 10,255,994)

111. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 110.

112. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claims 1-8 of the ’994 patent under at least 35 U.S.C. § 271(a), (b), and (c).

113. Upon information and belief, Sotera has directly infringed one or more claims of the ’994 patent through manufacture use, sale, offer for sale, and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.

114. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera’s customers to infringe one or more claims of the ’994 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.

115. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 1 of the ’994 patent. The ViSi Mobile Monitoring System is a system configured to reduce a frequency of alarms from a physiological monitoring system. The ViSi Mobile Monitoring System includes a ViSi Mobile Monitor having a physiological sensor configured to detect signals representative of a physiological condition of a patient. The ViSi Mobile Monitor includes one or more processors configured to receive the detected signals and determine a physiological parameter of the patient. The one or more processors of the ViSi Mobile Monitor is further configured to detect an alarm condition for the physiological parameter and delay a notification of the alarm condition until the alarm condition persists for a predetermined alarm notification delay time. The one or more processors of the ViSi Mobile Monitor is configured to provide a notification of the alarm condition responsive to the alarm condition persisting through the alarm notification delay time. The one or more processors of the ViSi Mobile Monitor

is associated with a care unit. The ViSi Mobile Monitor also includes a reporting module configured to simulate, using measurements obtained from the care unit, different alarm notification delay times to determine whether any of the different alarm notification delay times would have resulted in an alarm notification event. The alarm notification event for each different alarm notification delay time indicates that an alarm condition persisted for at least that alarm notification delay time. The reporting module of the ViSi Mobile Monitor is configured to provide an indicator of the effect of a change in alarm notification delay time on frequency of alarm notification events. The indicator is indicative of a change in the alarm notification delay time that is effective to reduce the frequency of transient or false alarms. The indicator is configured to be used to program one or more physiological monitoring systems with alarm notification delay times.

116. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the '994 patent by hiring former Masimo employees and after previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the '994 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the '994 patent no later than the filing of this Complaint.

117. Upon information and belief, Sotera and Foxconn have actively induced others to infringe the '994 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the '994 patent. To that end, Sotera provides instructions and teachings to its customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the

’994 patent. Sotera’s acts and Foxconn’s acts constitute infringement of the ’994 patent in violation of 35 U.S.C. § 271(b).

118. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of the ’994 patent. By way of example only, upon information and belief, Sotera actively induces direct infringement of the ’994 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the ViSi Mobile Monitor. Upon information and belief, Sotera and Foxconn knew or should have known that these activities would cause direct infringement.

119. Upon information and belief, Sotera’s acts and Foxconn’s acts constitute contributory infringement of the ’994 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, Sotera and Foxconn contributorily infringe because, among other things, Sotera offers to sell and/or sells within the United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the ’994 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the ’994 patent.

120. Upon information and belief, Sotera’s and Foxconn’s infringement of the ’994 patent has been, and continues to be, willful, deliberate, and intentional by continuing its acts of infringement after becoming aware of the ’994 patent and its infringement thereof, thus acting in reckless disregard of Masimo’s patent rights.

121. As a consequence of Sotera’s and Foxconn’s infringement of the ’994 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

122. Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

NINTH CLAIM FOR RELIEF

(Infringement of U.S. Patent No. RE47,353)

123. Masimo realleges and reincorporates the allegations set forth in paragraphs 1 through 122.

124. Upon information and belief, Sotera products, including at least the ViSi Mobile Monitoring System products, infringe at least Claims 1-2, 5-9, 13-15, 18-25 of the RE353 patent under at least 35 U.S.C. § 271(a), (b), and (c).

125. Upon information and belief, Sotera has directly infringed one or more claims of the RE353 patent through manufacture use, sale, offer for sale, and/or importation into the United States of medical monitoring devices, including the ViSi Mobile Monitoring System.

126. Upon information and belief, Foxconn has directly infringed or induced Sotera and/or Sotera's customers to infringe one or more claims of the RE353 patent. For example, on information and belief Foxconn has directed Sotera to manufacture use, sell, offer for sale, and/or import into the United States, electronic patient monitoring systems, including the ViSi Mobile Monitoring System.

127. For example, the ViSi Mobile Monitor of the ViSi Mobile Monitoring System includes all of the limitations of Claim 1 of the RE353 patent. The ViSi Mobile Monitor system is a physiological measurement system including a ViSi Mobile Monitor. The ViSi Mobile Monitor includes a noninvasive physiological sensor at its thumb sensor configured to be positioned on a patient and output a signal responsive to a physiological condition of the patient. The ViSi Mobile Monitor includes one or more processors in

communication with the noninvasive physiological sensor. The one or more processors of the ViSi Mobile Monitor is configured to electronically process the signal to determine a measurement of a physiological parameter based at least in part upon the signal and determine that an alarm should be activated in response to the measurement of the physiological parameter satisfying an alarm activation threshold. The one or more processors of the ViSi Mobile Monitor is also configured to electronically determine that an alarm suspension should be initiated for a parameter-specific alarm suspension period of time corresponding to the physiological parameter. The parameter-specific alarm suspension period of time is one of at least a plurality of parameter-specific alarm suspension periods of time, and the parameter-specific alarm suspension period of time is different from at least one other parameter-specific alarm suspension period of time corresponding to at least one other physiological parameter for which the one or more processors are configured to determine at least one measurement. The one or more processors of the ViSi Mobile Monitor is configured to electronically suspend the alarm for the parameter-specific alarm suspension period of time and activate the alarm when the measurement of the physiological parameter satisfies the alarm activation threshold after the parameter-specific alarm suspension period of time has passed.

128. Upon information and belief, Sotera and Foxconn have monitored Masimo's patents, including the RE353 patent by hiring former Masimo employees and after previous trade secret misappropriation litigation asserted against Sotera by Masimo. Upon further information and belief, through the knowledge of the RE353 patent gained by monitoring Masimo's patents, Sotera and Foxconn knew or should have known that these activities would cause direct infringement. Sotera and Foxconn also had knowledge of the RE353 patent no later than the filing of this Complaint.

129. Upon information and belief, Sotera and Foxconn have actively induced others to infringe the RE353 patent by marketing and selling the above ViSi Mobile Monitoring Systems, knowing and intending that such systems would be used by customers and end users in a manner that infringes the RE353 patent. To that end, Sotera provides instructions and teachings to its customers and end users that such ViSi Mobile Monitoring Systems be used to infringe the RE353 patent. Sotera's acts and Foxconn's acts constitute infringement of the RE353 patent in violation of 35 U.S.C. § 271(b).

130. Upon information and belief, Sotera and Foxconn actively induce health-care service providers and users to directly infringe the asserted claims of the RE353 patent. By way of example only, upon information and belief, Sotera and Foxconn actively induce direct infringement of the RE353 patent by providing directions, demonstrations, guides, manuals, training for use, and/or other materials necessary for the use, refurbishing, and/or servicing of the ViSi Mobile Monitor. Upon information and belief, Sotera and Foxconn knew or should have known that these activities would cause direct infringement.

131. Upon information and belief, Sotera's acts and Foxconn's acts constitute contributory infringement of the RE353 patent in violation of 35 U.S.C. § 271(c). Upon information and belief, Sotera contributorily infringes because, among other things, Sotera offers to sell and/or sells within the United States, and/or imports into the United States, components of the ViSi Mobile Monitoring System that constitute material parts of the invention of the asserted claims of the RE353 patent, are not staple articles or commodities of commerce suitable for substantial non-infringing use, and are known by Sotera and Foxconn to be especially made or especially adapted for use in an infringement of the RE353 patent.

132. Upon information and belief, Sotera's and Foxconn's infringement of the RE353 patent has been, and continues to be, willful, deliberate, and

intentional by continuing its acts of infringement after becoming aware of the RE353 patent and its infringement thereof, thus acting in reckless disregard of Masimo's patent rights.

133. As a consequence of Sotera's and Foxconn's infringement of the RE353 patent, Masimo has suffered and will continue to suffer irreparable harm and injury, including monetary damages in an amount to be determined at trial.

134. Upon information and belief, unless enjoined, Sotera, Foxconn, and/or others acting on behalf of Sotera, will continue their infringing acts, thereby causing additional irreparable injury to Masimo for which there is no adequate remedy at law.

IX. PRAYER FOR RELIEF

WHEREFORE, Plaintiff Masimo prays for judgment and seeks relief as follows:

(1) Pursuant to 35 U.S.C. § 271, a determination that Sotera, Foxconn, and their officers, agents, servants, employees, attorneys and all others in active concert and/or participation with them have infringed each of the'735, '300, '623, RE218, RE244, RE249, '108, '994, and RE353 patents through the manufacture, use, importation, offer for sale, and/or sale of infringing products and/or any of the other acts prohibited by 35 U.S.C. § 271;

(2) Pursuant to 35 U.S.C. § 283, an injunction enjoining Sotera, Foxconn, and their officers, agents, servants, employees, attorneys and all others in active concert and/or participation with them from infringing the '735, '300, '623, RE218, RE244, RE249, '108, '994, and RE353 patents through the manufacture, use, importation, offer for sale, and/or sale of infringing products and/or any of the other acts prohibited by 35 U.S.C. § 271, including preliminary and permanent injunctive relief;

(3) Pursuant to 35 U.S.C. § 284, an award of compensating Masimo for Sotera's and Foxconn's infringement of the '735, '300, '623, RE218,

RE244, RE249, ’108, ’994, and RE353 patents through payment of not less than a reasonable royalty on Sotera’s sales of infringing products;

(4) Pursuant to 35 U.S.C. § 284, an award increasing damages up to three times the amount found or assessed by the jury for Sotera’s and Foxconn’s infringement of each of the ’735, ’300, ’623, RE218, RE244, RE249, ’108, ’994, and RE353 patents in view of the willful and deliberate nature of the infringement;

(5) Pursuant to 35 U.S.C. § 285, a finding that this is an exceptional case, and an award of reasonable attorneys’ fees and non-taxable costs;

(6) An assessment of prejudgment and post-judgment interest and costs against Sotera and Foxconn, together with an award of such interest and costs, pursuant to 35 U.S.C. § 284;

(7) An award of taxable costs; and

(8) That Masimo be granted such other and further relief as the Court deems equitable and just in the circumstances.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 12, 2019

By: /s/ *Brian C. Claassen*
Joseph R. Re
Stephen C. Jensen
Irfan A. Lateef
Brian C. Claassen

Attorneys for Plaintiff
MASIMO CORPORATION

DEMAND FOR JURY TRIAL

Pursuant to Rule 38(b) of the Federal Rules of Civil Procedure, Plaintiff Masimo Corporation demands a trial by jury of all issues raised by the pleadings which are triable by jury.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: June 12, 2019

By: /s/ *Brian C. Claassen*
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MASIMO CORPORATION

TABLE OF EXHIBITS

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30465573

US009788735B2

(12) **United States Patent**
Al-Ali

(10) **Patent No.: US 9,788,735 B2**
(45) **Date of Patent: *Oct. 17, 2017**

(54) **BODY WORN MOBILE MEDICAL PATIENT MONITOR**

(71) Applicant: **MASIMO CORPORATION**, Irvine, CA (US)

(72) Inventor: **Ammar Al-Ali**, San Juan Capistrano, CA (US)

(73) Assignee: **MASIMO CORPORATION**, Irvine, CA (US)

(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/499,619**

(22) Filed: **Apr. 27, 2017**

(65) **Prior Publication Data**

US 2017/0224233 A1 Aug. 10, 2017

Related U.S. Application Data

(63) Continuation of application No. 15/448,989, filed on Mar. 3, 2017, which is a continuation of application (Continued)

(51) **Int. Cl.**
A61B 5/1455 (2006.01)
A61B 5/0205 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/0205*** (2013.01); ***A61B 5/0024*** (2013.01); ***A61B 5/021*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC ... A61B 5/0002; A61B 5/0004; A61B 5/0024; A61B 5/02; A61B 5/0205; A61B 5/0402;
(Continued)

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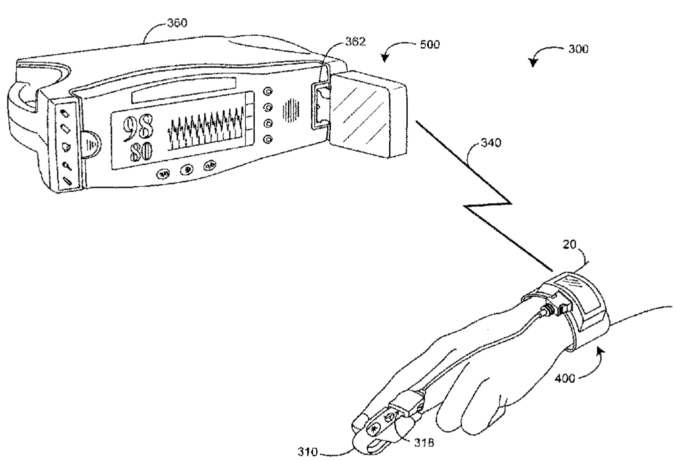
Primary Examiner — Eric Winakur
(74) *Attorney, Agent, or Firm* — Knobbe Martens Olson & Bear LLP

(57) **ABSTRACT**

A body worn mobile medical monitoring device configured to minimize cable wiring from a sensor by placement of one or more sensor communication ports. The body worn mobile medical monitoring device includes a housing securable on a lower arm of a patient, a display, and a sensor communication port positioned on a side of the housing and configured to face a hand of the lower arm of the patient when the mobile medical monitoring device is mounted to the lower arm of the patient. The sensor communication port provides wired communication with a pulse oximetry sensor attached to a digit of the hand of the patient, and is positioned on the side of the housing such that a path from the port on the side of the housing to the digit of the patient is shorter than any other path from any other side of the housing to the digit.

20 Claims, 17 Drawing Sheets



Related U.S. Application Data

No. 14/815,232, filed on Jul. 31, 2015, now abandoned, which is a continuation of application No. 14/217,788, filed on Mar. 18, 2014, now Pat. No. 9,113,832, which is a continuation of application No. 14/037,137, filed on Sep. 25, 2013, now Pat. No. 9,113,831, which is a continuation of application No. 12/955,826, filed on Nov. 29, 2010, now Pat. No. 8,548,548, which is a continuation of application No. 11/417,006, filed on May 3, 2006, now Pat. No. 7,844,315, which is a continuation of application No. 11/048,330, filed on Feb. 1, 2005, now Pat. No. 7,844,314, which is a continuation of application No. 10/377,933, filed on Feb. 28, 2003, now Pat. No. 6,850,788.

(60) Provisional application No. 60/367,428, filed on Mar. 25, 2002.

(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 5/021 (2006.01)
A61B 5/0404 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 5/0404*** (2013.01); ***A61B 5/14552*** (2013.01); ***A61B 5/6824*** (2013.01); ***A61B 5/6826*** (2013.01); ***A61B 5/6831*** (2013.01); *A61B 2562/222* (2013.01); *A61B 2562/227* (2013.01)

(58) **Field of Classification Search**
CPC . A61B 5/1455; A61B 5/14551; A61B 5/6825; A61B 5/6826; A61B 5/6831; A61B 5/72; A61B 2560/0443; A61B 2562/06
See application file for complete search history.

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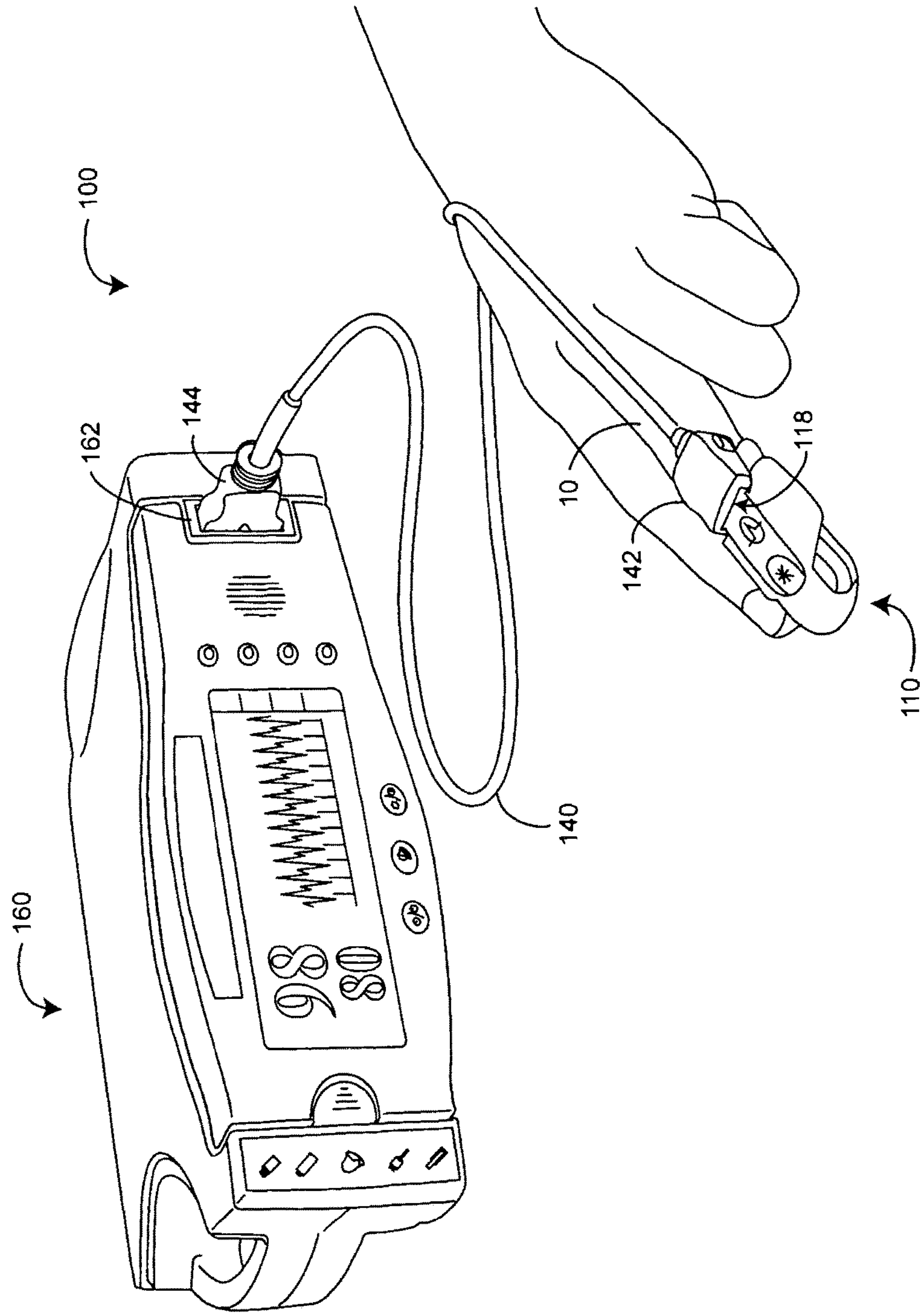


FIG. 1 (Prior Art)

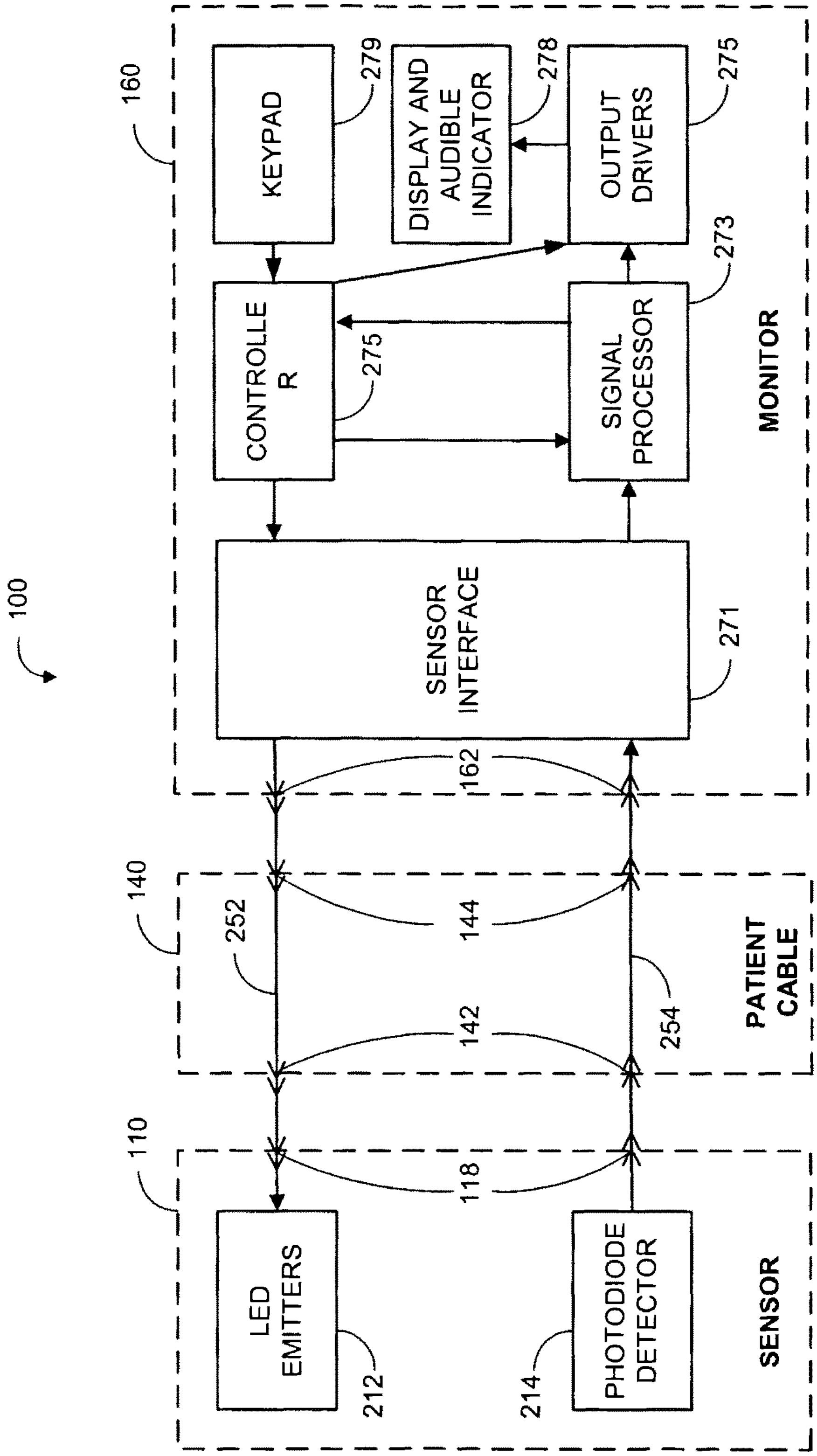


FIG. 2 (Prior Art)

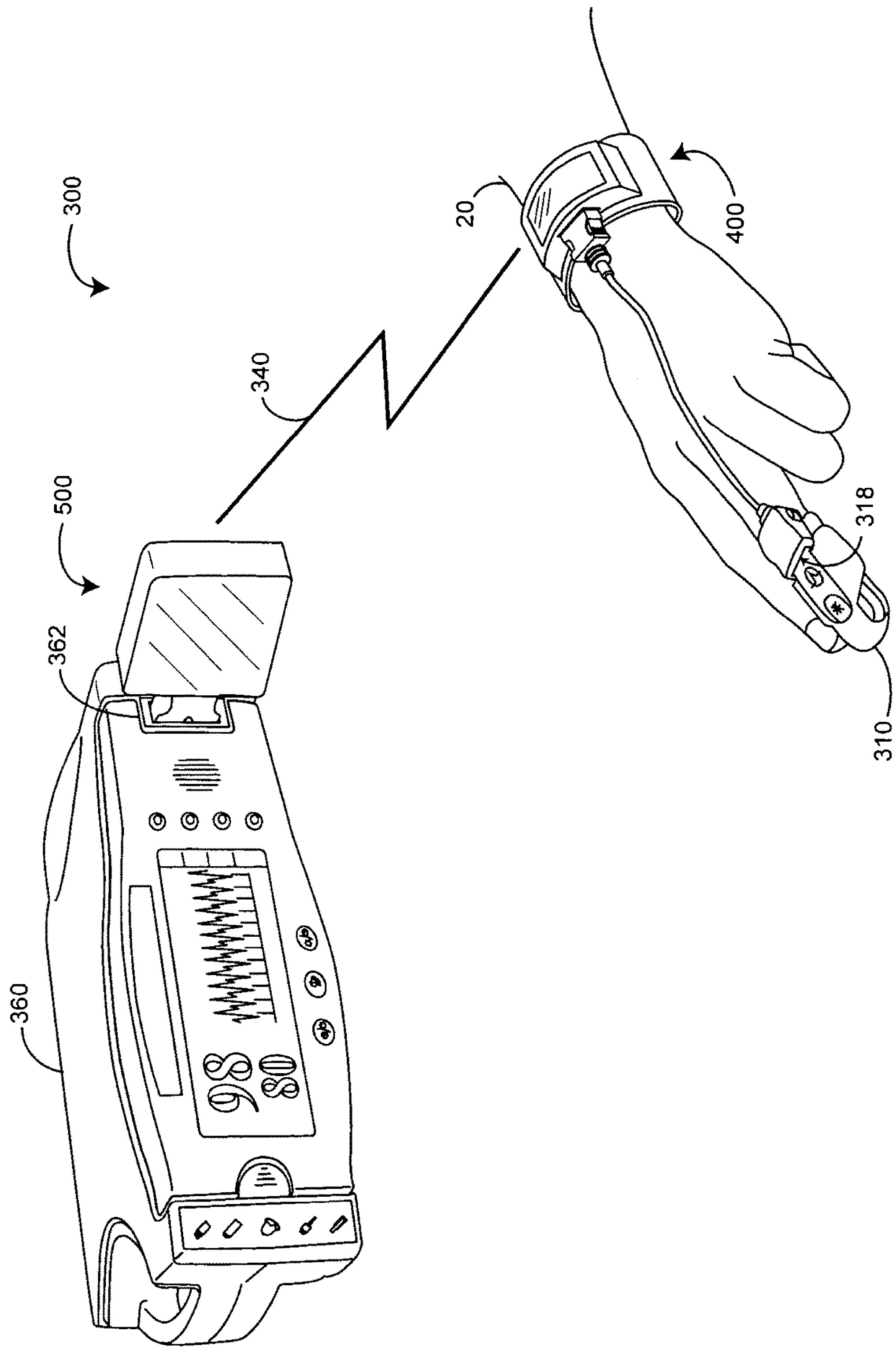


FIG. 3

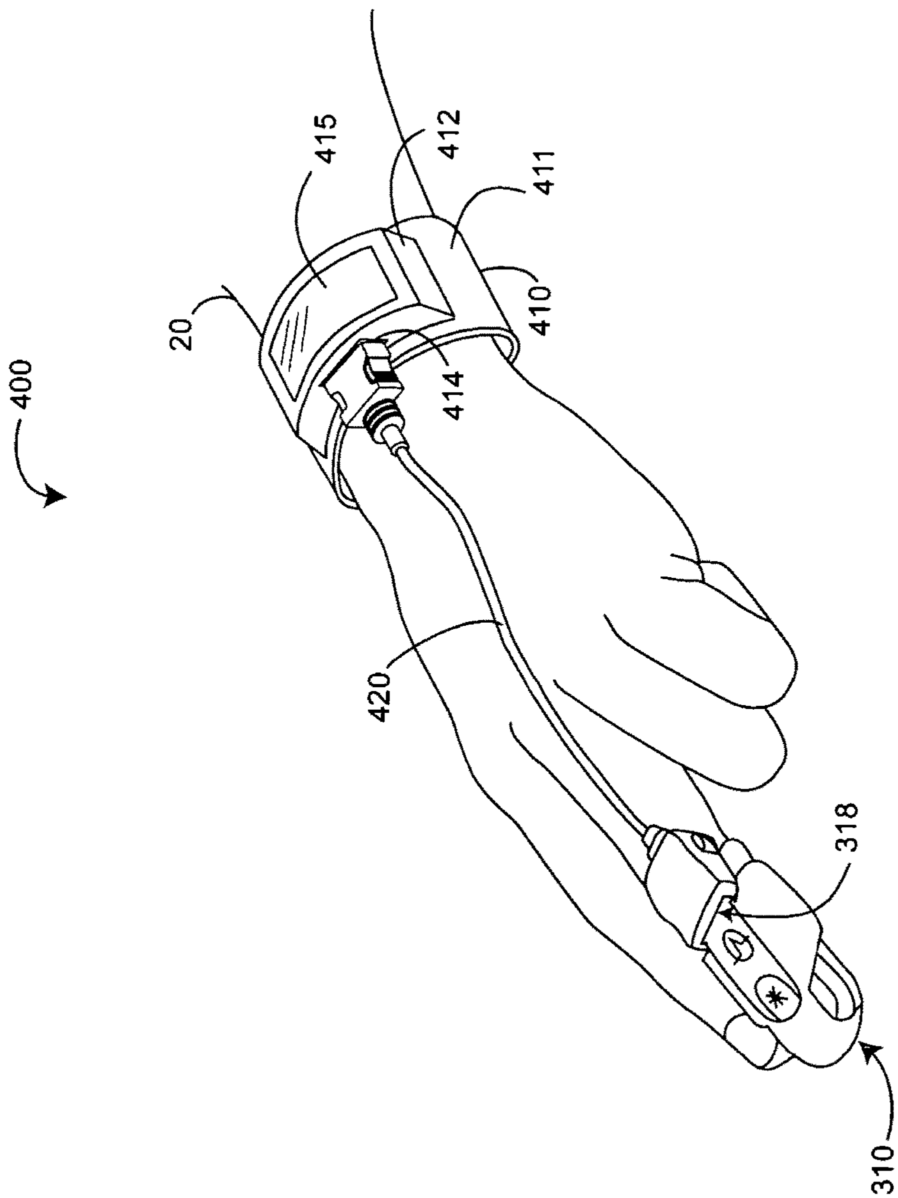


FIG. 4A

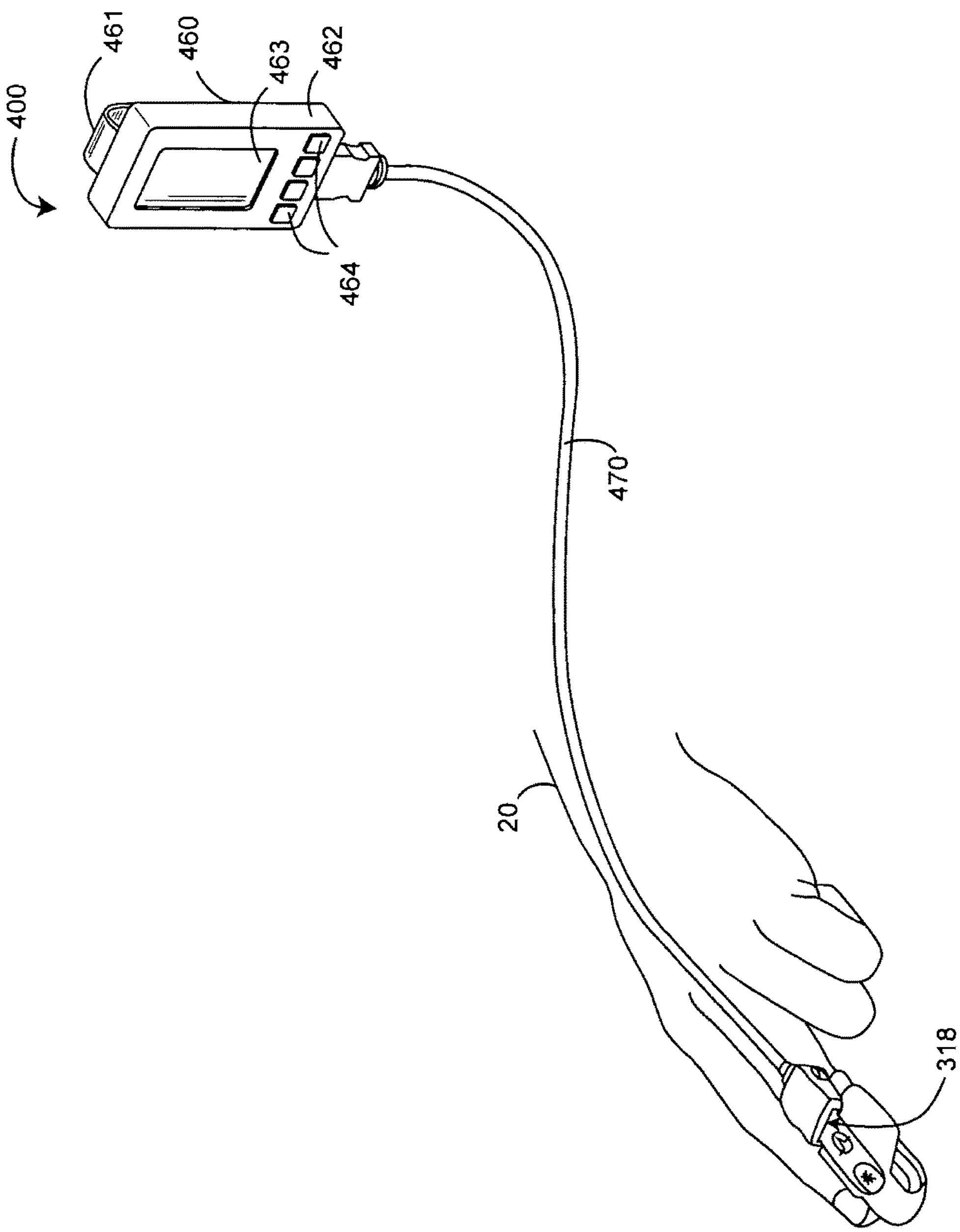


FIG. 4B

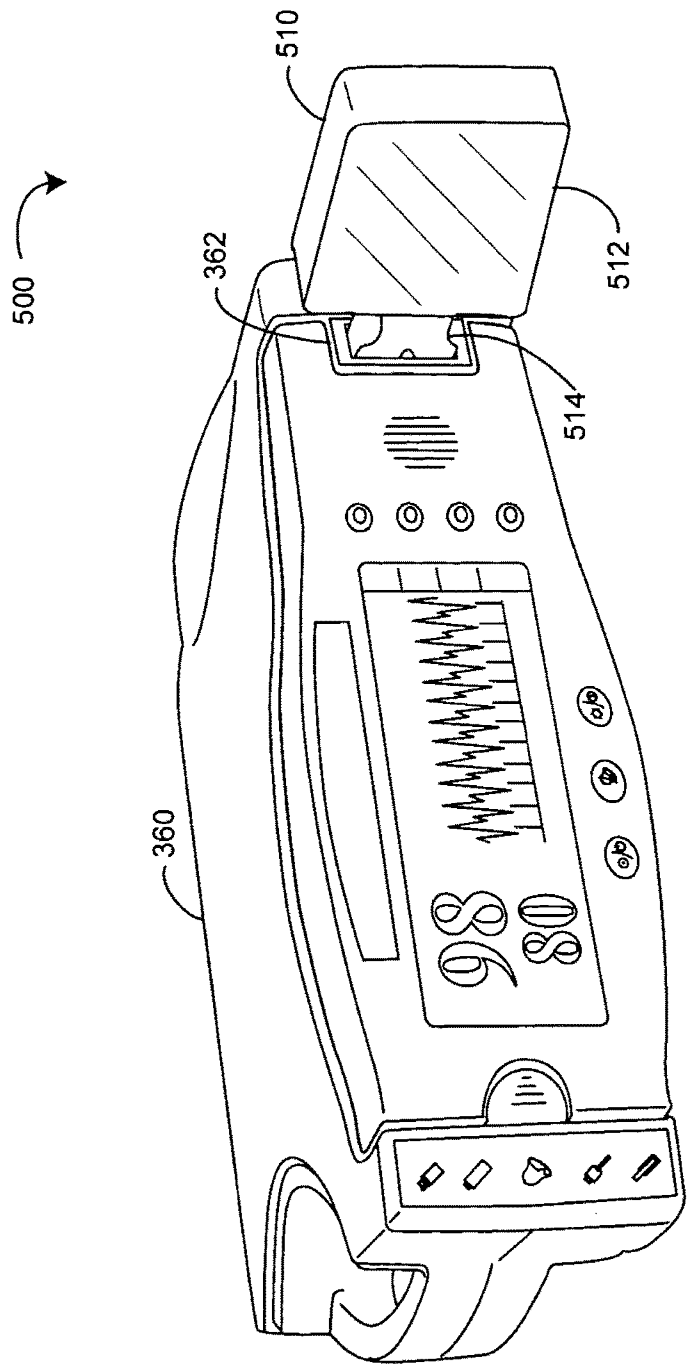


FIG. 5A

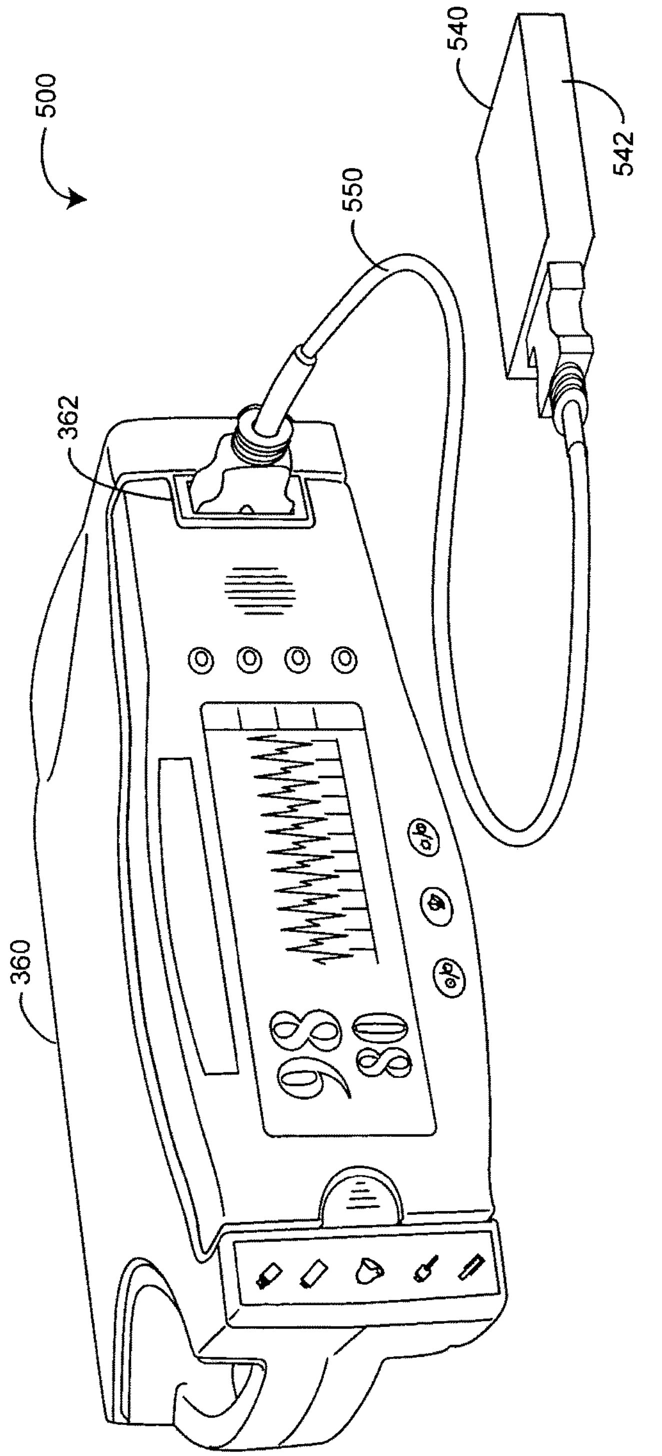


FIG. 5B

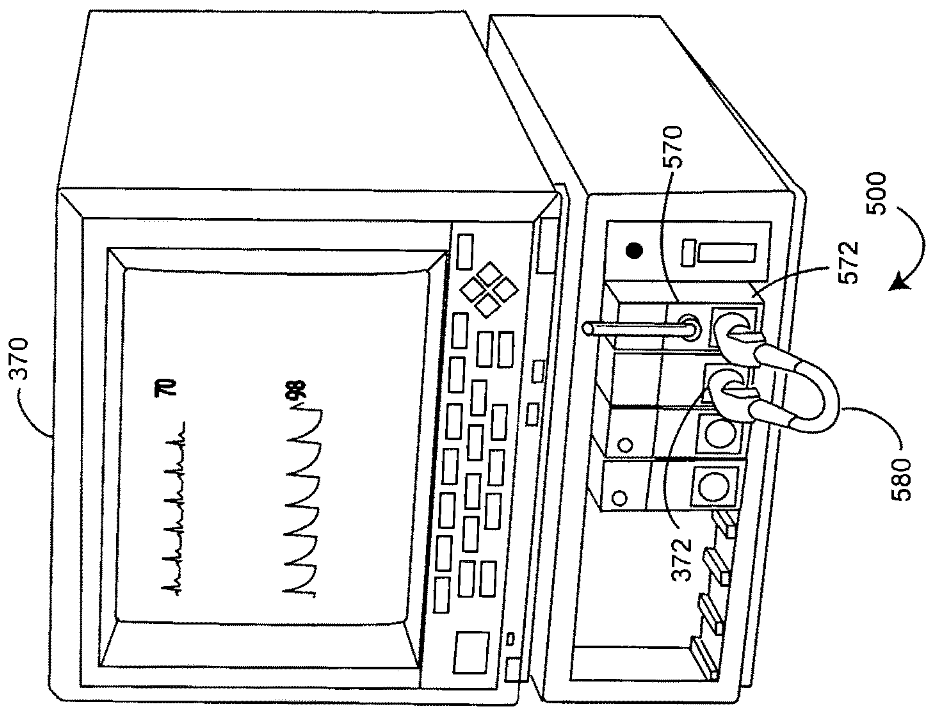


FIG. 5C

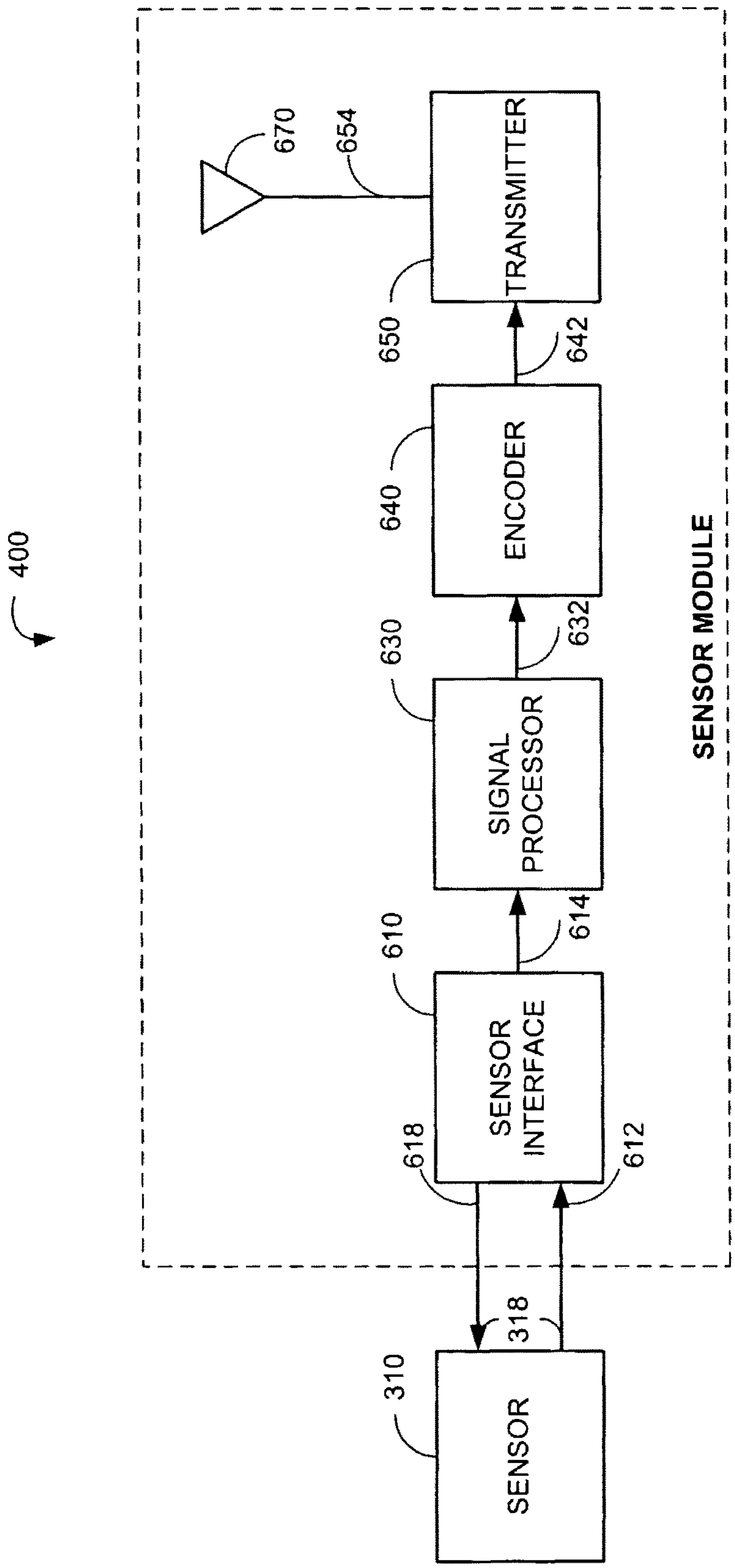

400
670
654
TRANSMITTER
650
642
ENCODER
640
632
630
SIGNAL PROCESSOR
614
610
SENSOR INTERFACE
618
612
SENSOR MODULE
318
310
SENSOR

FIG. 6

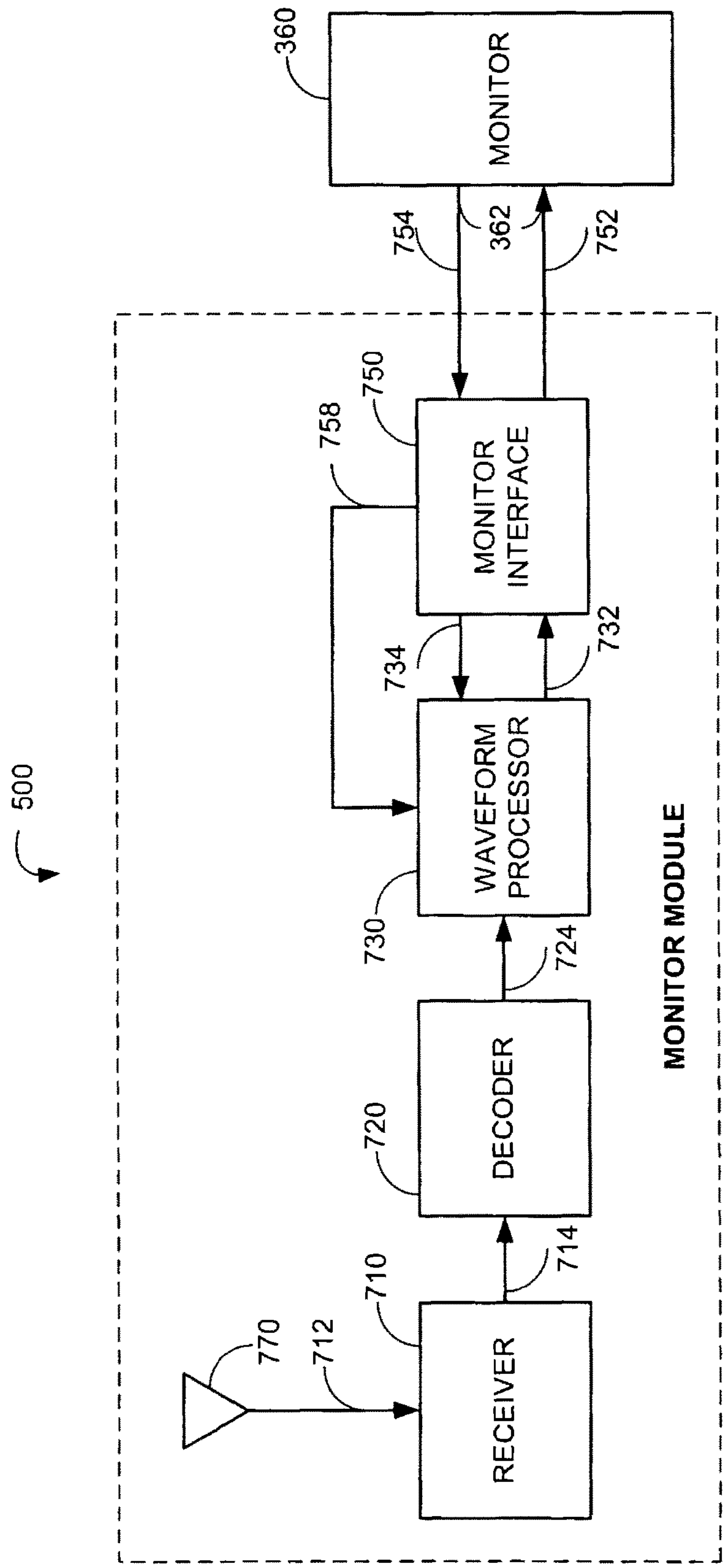

500
MONITOR MODULE
RECEIVER
DECODER
WAVEFORM PROCESSOR
MONITOR INTERFACE
MONITOR
360
362
752
754
750
758
732
734
730
724
720
714
710
712
770

FIG. 7

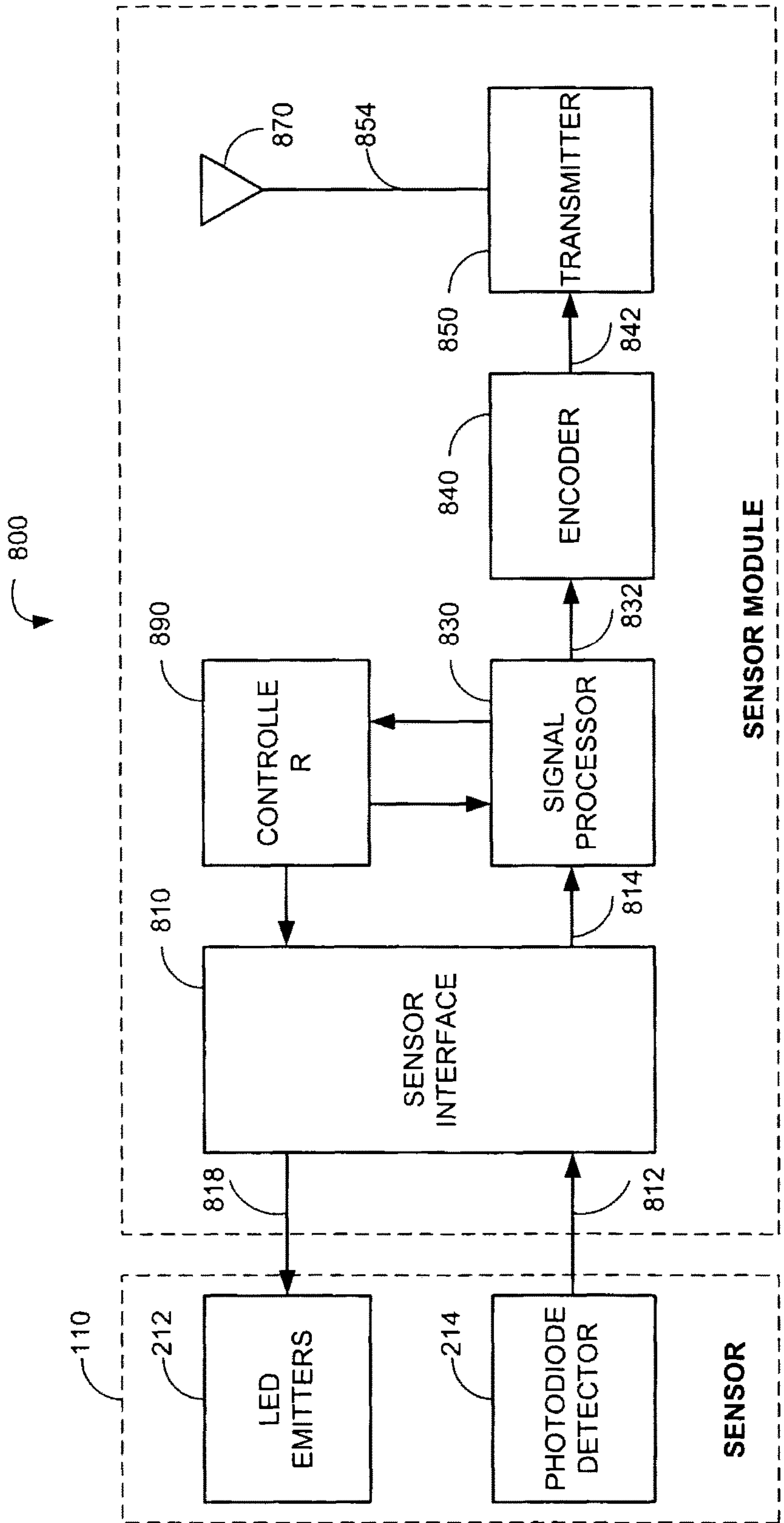

800
870
854
850
TRANSMITTER
842
ENCODER
840
832
830
890
CONTROLLE R
SIGNAL PROCESSOR
814
810
SENSOR INTERFACE
818
812
SENSOR MODULE
110
212
LED EMITTERS
214
PHOTODIODE DETECTOR
SENSOR

FIG. 8

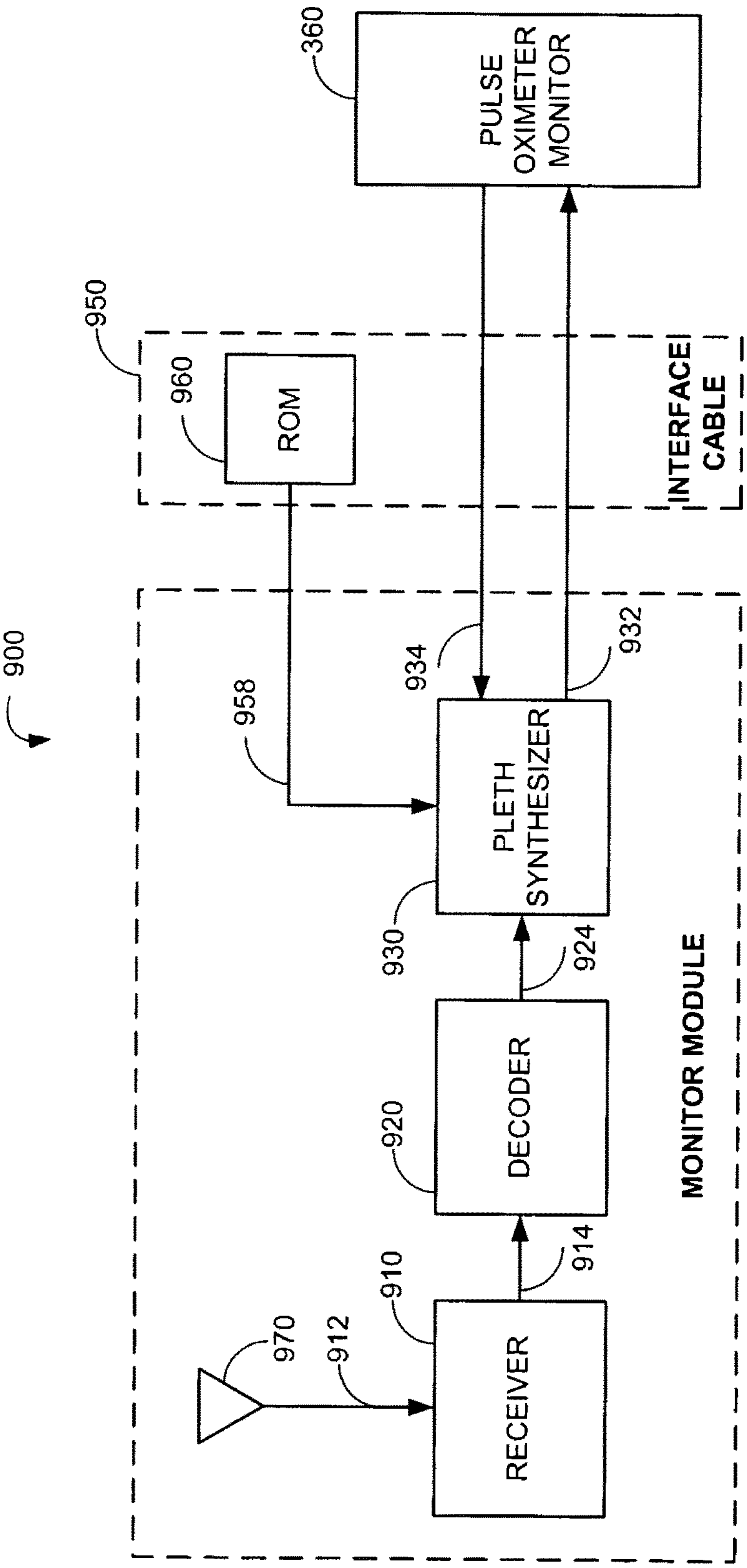

360
PULSE
OXIMETER
MONITOR
950
960
ROM
INTERFACE
CABLE
900
958
934
932
PLETH
SYNTHESIZER
930
924
DECODER
920
914
910
970
912
RECEIVER
MONITOR MODULE

FIG. 9

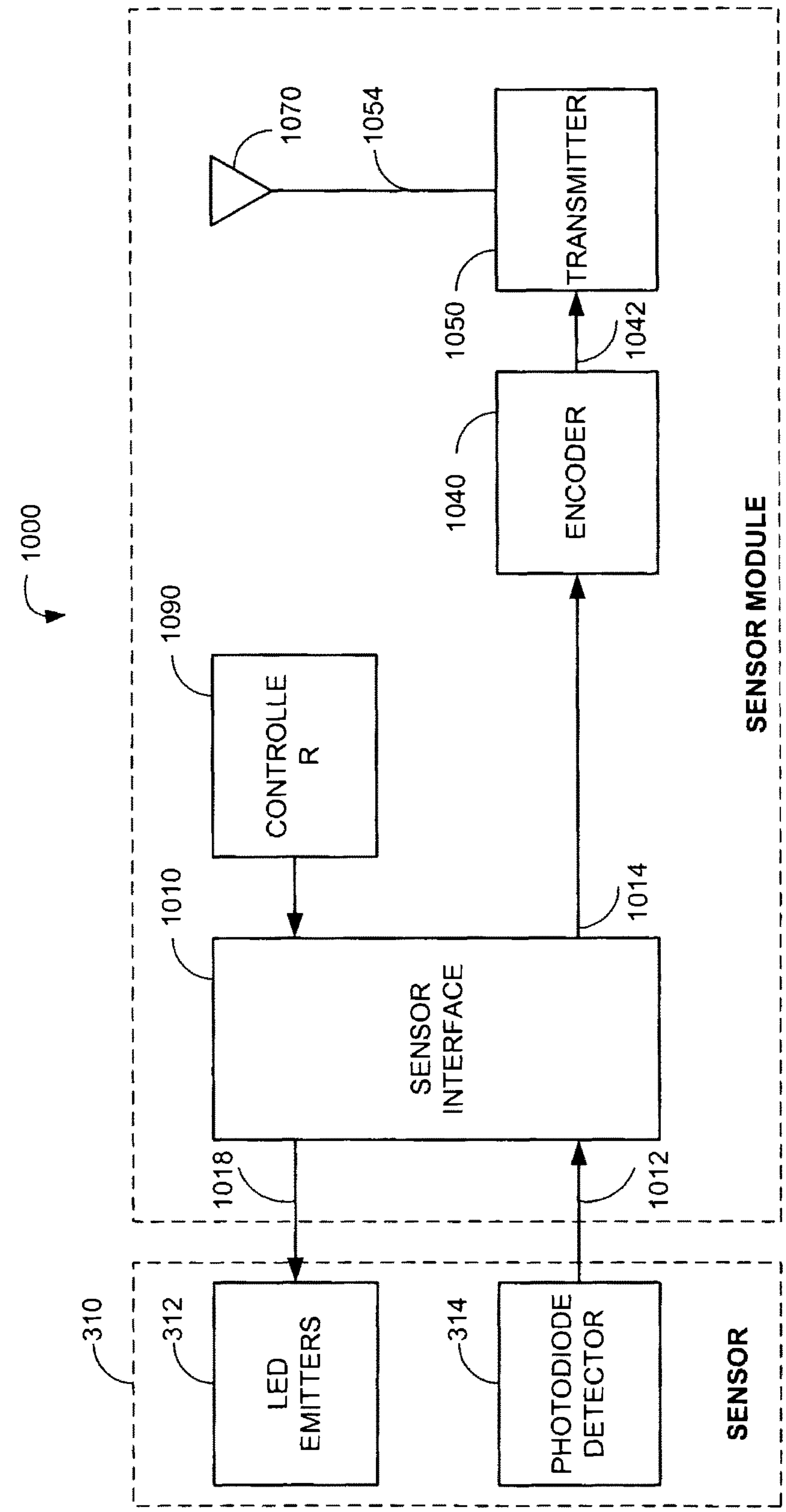

1000
SENSOR MODULE
1070
1054
TRANSMITTER
1050
1042
ENCODER
1040
1090
CONTROLLE
R
1010
1014
SENSOR
INTERFACE
1018
1012
310
312
LED
EMITTERS
314
PHOTODIODE
DETECTOR
SENSOR

FIG. 10

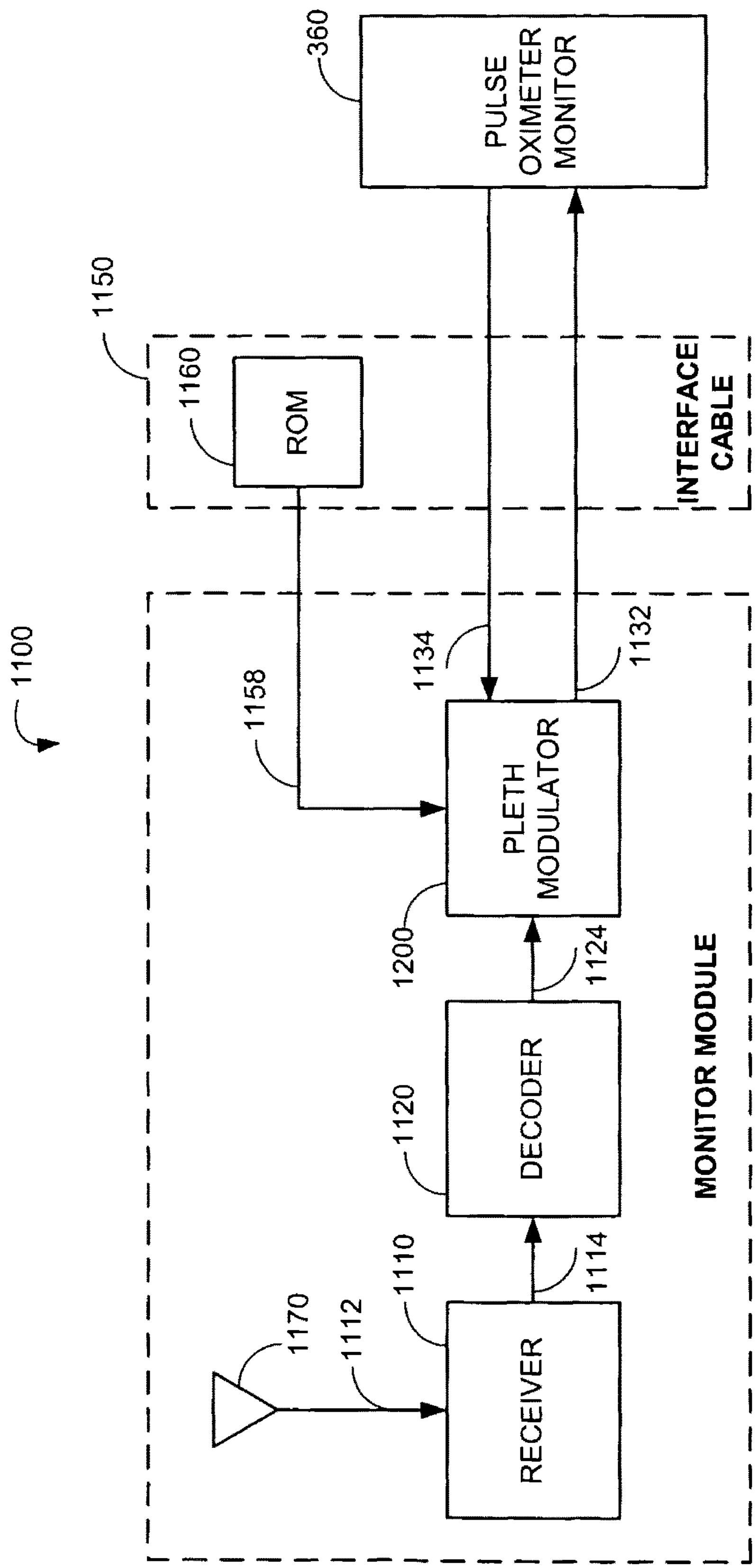
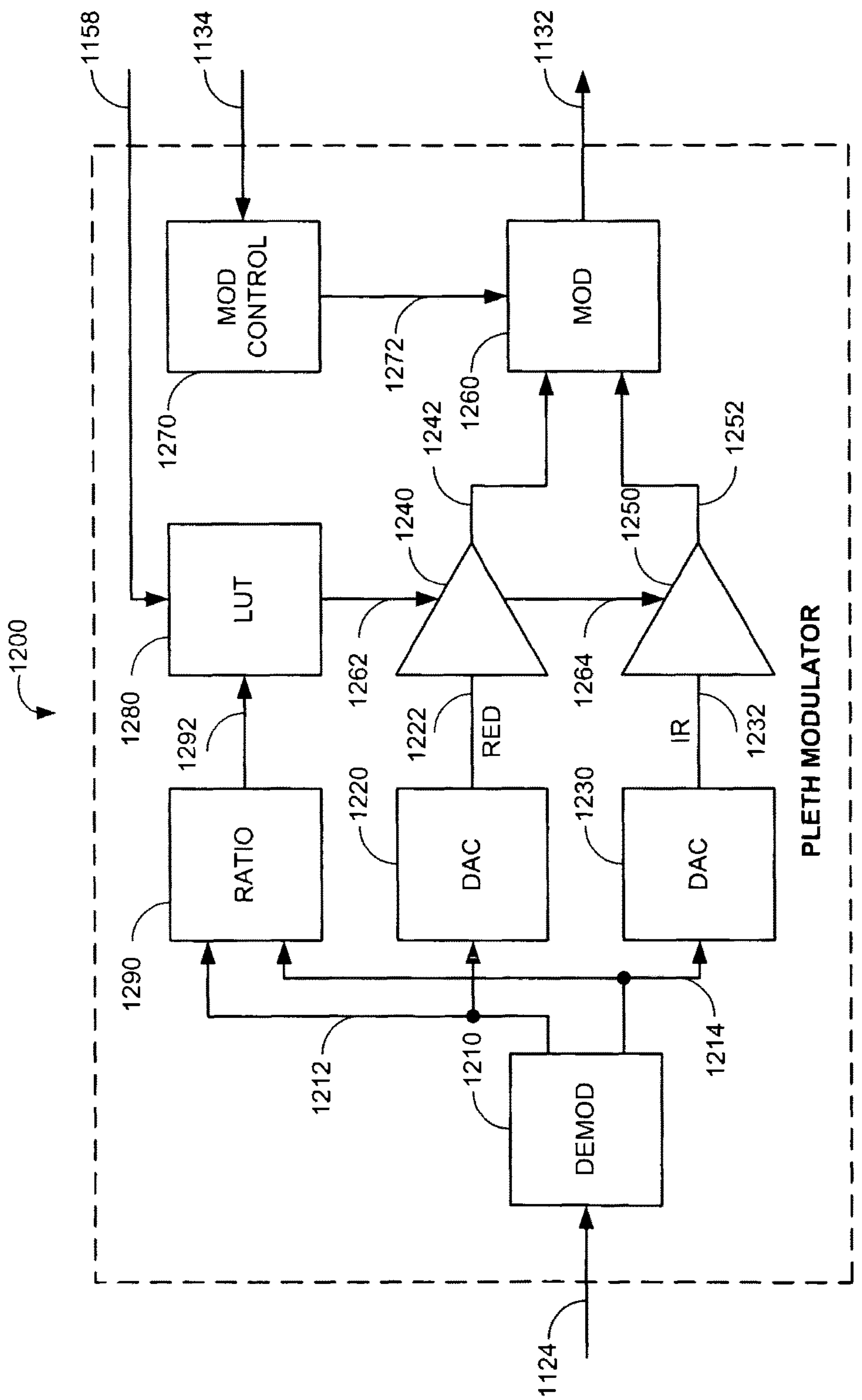

360
PULSE OXIMETER MONITOR
1150
1160
ROM
INTERFACE CABLE
1100
1158
1134
1132
PLETH MODULATOR
1200
1124
DECODER
1120
MONITOR MODULE
1110
1114
1170
1112
RECEIVER

FIG. 11



1158
1134
1132
MOD CONTROL
MOD
1270
1272
1260
1242
1252
LUT
1240
1250
1200
1280
1262
1264
PLETH MODULATOR
1292
1222
RED
IR
1232
RATIO
1220
DAC
1230
DAC
1290
1212
1210
1214
DEMOD
1124

FIG. 12

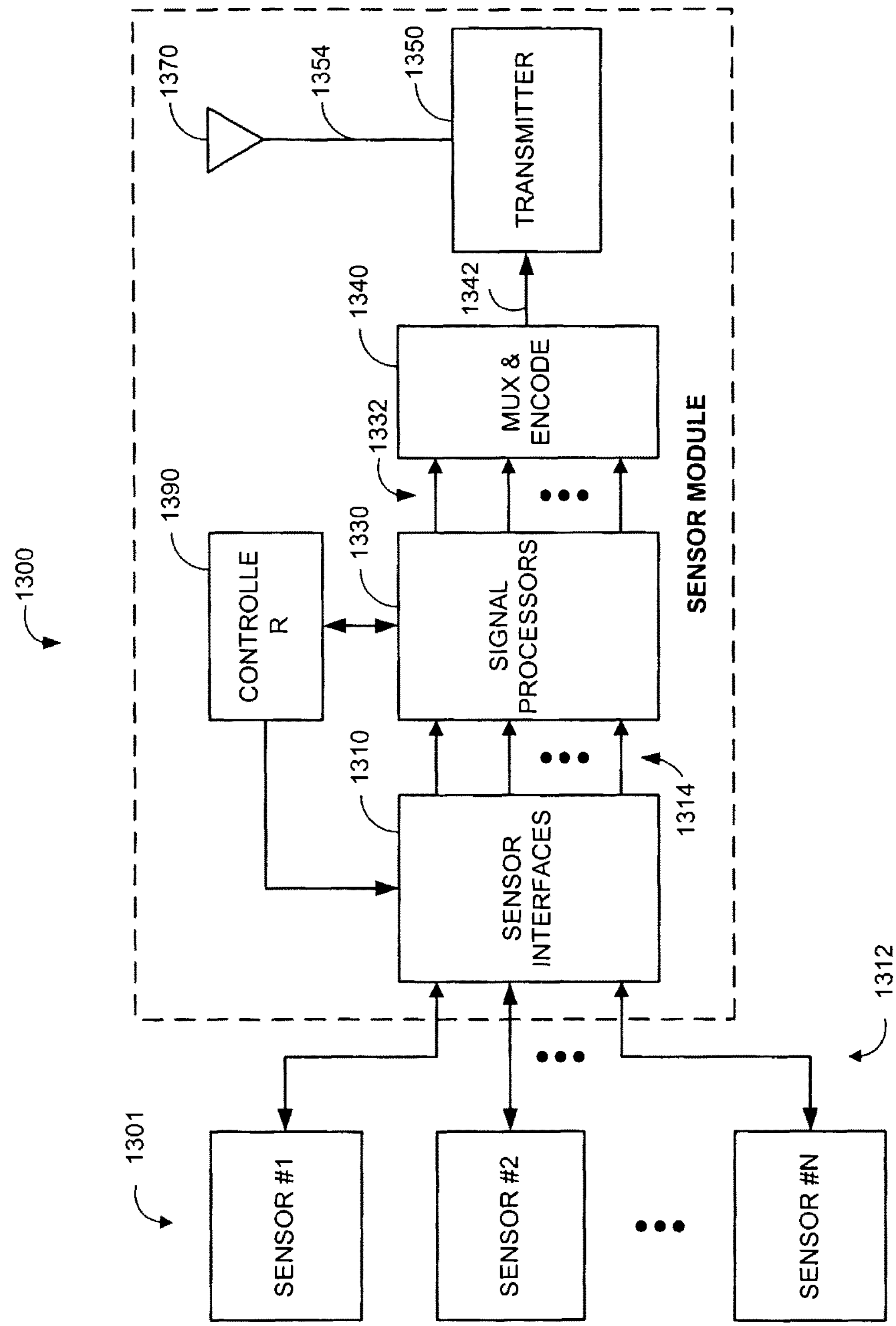

1300
1370
1354
1350
TRANSMITTER
1340
1342
MUX & ENCODE
1332
1390
CONTROLLE R
1330
SIGNAL PROCESSORS
1310
SENSOR INTERFACES
1314
SENSOR MODULE
1301
SENSOR #1
SENSOR #2
SENSOR #N
1312

FIG. 13

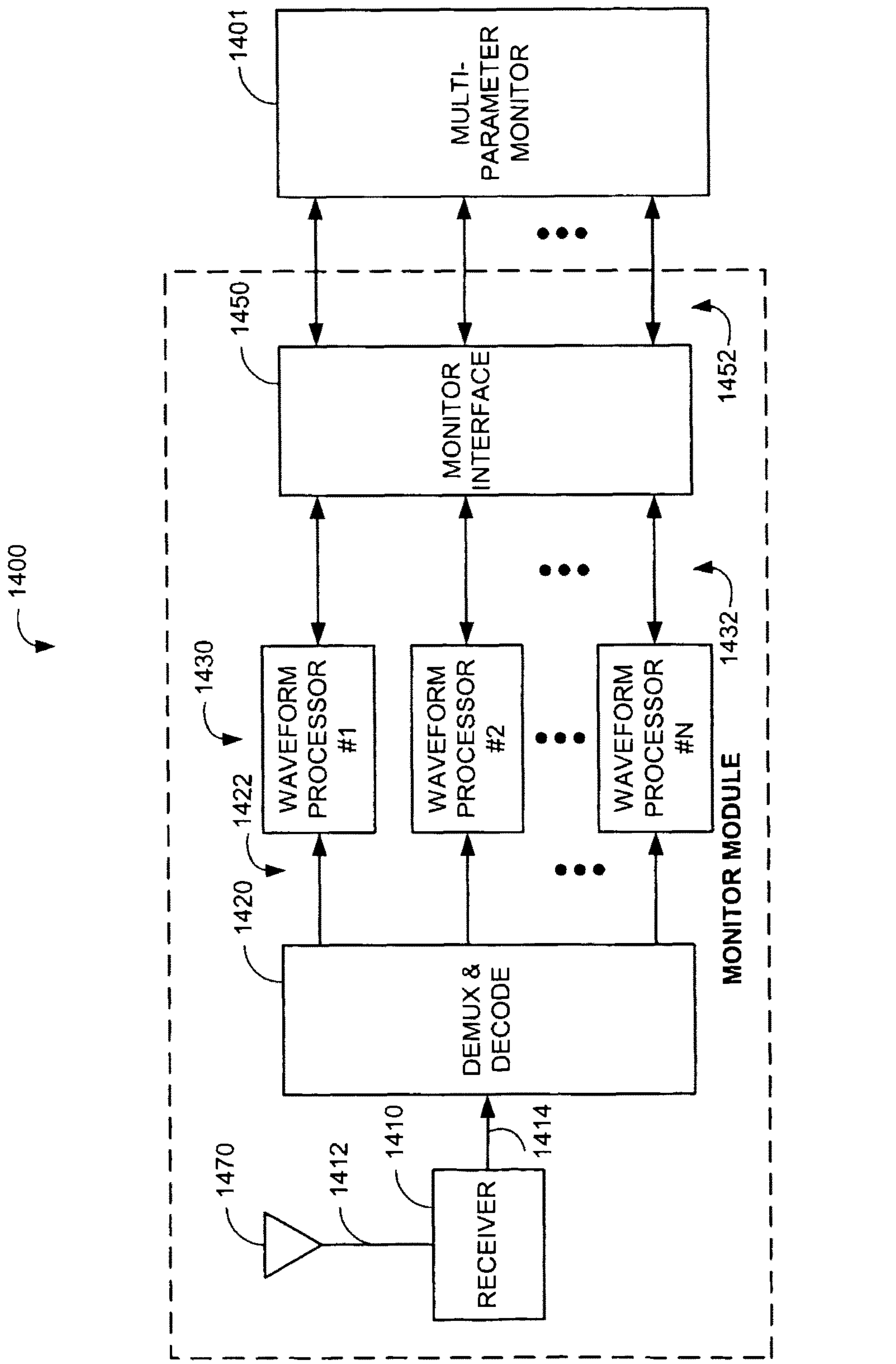

1400
1401
MULTI-
PARAMETER
MONITOR
1450
MONITOR
INTERFACE
1452
1430
WAVEFORM
PROCESSOR
#1
WAVEFORM
PROCESSOR
#2
WAVEFORM
PROCESSOR
#N
1432
1422
1420
DEMUX &
DECODE
MONITOR MODULE
1470
1412
1410
1414
RECEIVER

FIG. 14

BODY WORN MOBILE MEDICAL PATIENT MONITOR

REFERENCE TO RELATED APPLICATION

The present application is a continuation of U.S. patent application Ser. No. 15/448,989, filed on Mar. 3, 2017, entitled "Physiological Measurement Communications Adapter," which is a continuation of U.S. patent application Ser. No. 14/815,232, filed on Jul. 31, 2015, entitled "Physiological Measurement Communications Adapter," which is a continuation of U.S. patent application Ser. No. 14/217,788, filed on Mar. 18, 2014, entitled "Wrist-Mounted Physiological Measurement Device," now U.S. Pat. No. 9,113,832, which is a continuation of U.S. patent application Ser. No. 14/037,137, filed on Sep. 25, 2013, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 9,113,831, which is a continuation of U.S. patent application Ser. No. 12/955,826, filed on Nov. 29, 2010, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 8,548,548, which is a continuation of U.S. patent application Ser. No. 11/417,006, filed on May 3, 2006, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 7,844,315, which claims priority benefit under 35 U.S.C. §120 to, and is a continuation of, U.S. patent application Ser. No. 11/048,330, filed Feb. 1, 2005, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 7,844,314, which is a continuation of U.S. patent application Ser. No. 10/377,933, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 6,850,788, which claims priority benefit under 35 U.S.C. §119(e) from U.S. Provisional Application No. 60/367,428, filed Mar. 25, 2002, entitled "Physiological Measurement Communications Adapter." The present application also incorporates the foregoing utility disclosures herein by reference.

BACKGROUND OF THE INVENTION

Patient vital sign monitoring may include measurements of blood oxygen, blood pressure, respiratory gas, and EKG among other parameters. Each of these physiological parameters typically requires a sensor in contact with a patient and a cable connecting the sensor to a monitoring device. For example, FIGS. **1-2** illustrate a conventional pulse oximetry system **100** used for the measurement of blood oxygen. As shown in FIG. **1**, a pulse oximetry system has a sensor **110**, a patient cable **140** and a monitor **160**. The sensor **110** is typically attached to a finger **10** as shown. The sensor **110** has a plug **118** that inserts into a patient cable socket **142**. The monitor **160** has a socket **162** that accepts a patient cable plug **144**. The patient cable **140** transmits an LED drive signal **252** (FIG. **2**) from the monitor **160** to the sensor **110** and a resulting detector signal **254** (FIG. **2**) from the sensor **110** to the monitor **160**. The monitor **160** processes the detector signal **254** (FIG. **2**) to provide, typically, a numerical readout of the patient's oxygen saturation, a numerical readout of pulse rate, and an audible indicator or "beep" that occurs in response to each arterial pulse.

As shown in FIG. **2**, the sensor **110** has both red and infrared LED emitters **212** and a photodiode detector **214**. The monitor **160** has a sensor interface **271**, a signal processor **273**, a controller **275**, output drivers **276**, a display and audible indicator **278**, and a keypad **279**. The monitor **160** determines oxygen saturation by computing the differential absorption by arterial blood of the two wavelengths emitted by the sensor emitters **212**, as is well-known in the

art. The sensor interface **271** provides LED drive current **252** which alternately activates the red and IR LED emitters **212**. The photodiode detector **214** generates a signal **254** corresponding to the red and infrared light energy attenuated from transmission through the patient finger **10** (FIG. **1**). The sensor interface **271** also has input circuitry for amplification, filtering and digitization of the detector signal **254**. The signal processor **273** calculates a ratio of detected red and infrared intensities, and an arterial oxygen saturation value is empirically determined based on that ratio. The controller **275** provides hardware and software interfaces for managing the display and audible indicator **278** and keypad **279**. The display and audible indicator **278** shows the computed oxygen status, as described above, and provides the pulse beep as well as alarms indicating oxygen desaturation events. The keypad **279** provides a user interface for setting alarm thresholds, alarm enablement, and display options, to name a few.

SUMMARY OF THE INVENTION

Conventional physiological measurement systems are limited by the patient cable connection between sensor and monitor. A patient must be located in the immediate vicinity of the monitor. Also, patient relocation requires either disconnection of monitoring equipment and a corresponding loss of measurements or an awkward simultaneous movement of patient equipment and cables. Various devices have been proposed or implemented to provide wireless communication links between sensors and monitors, freeing patients from the patient cable tether. These devices, however, are incapable of working with the large installed base of existing monitors and sensors, requiring caregivers and medical institutions to suffer expensive wireless upgrades. It is desirable, therefore, to provide a communications adapter that is plug-compatible both with existing sensors and monitors and that implements a wireless link replacement for the patient cable.

An aspect of a physiological measurement communications adapter comprises a sensor interface configured to receive a sensor signal. A transmitter modulates a first baseband signal responsive to the sensor signal so as to generate a transmit signal. A receiver demodulates a receive signal corresponding to the transmit signal so as to generate a second baseband signal corresponding to the first baseband signal. Further, a monitor interface is configured to communicate a waveform responsive to the second baseband signal to a sensor port of a monitor. The waveform is adapted to the monitor so that measurements derived by the monitor from the waveform are generally equivalent to measurements derivable from the sensor signal. The communications adapter may further comprise a signal processor having an input in communications with the sensor interface, where the signal processor is operable to derive a parameter responsive to the sensor signal and where the first baseband signal is responsive to the parameter. The parameter may correspond to at least one of a measured oxygen saturation and a pulse rate.

One embodiment may further comprise a waveform generator that synthesizes the waveform from a predetermined shape. The waveform generator synthesizes the waveform at a frequency adjusted to be generally equivalent to the pulse rate. The waveform may have a first amplitude and a second amplitude, and the waveform generator may be configured to adjusted the amplitudes so that measurements derived by the monitor are generally equivalent to a measured oxygen saturation.

In another embodiment, the sensor interface is operable on the sensor signal to provide a plethysmograph signal output, where the first baseband signal is responsive to the plethysmograph signal. This embodiment may further comprise a waveform modulator that modifies a decoded signal responsive to the second baseband signal to provide the waveform. The waveform modulator may comprise a demodulator that separates a first signal and a second signal from the decoded signal, an amplifier that adjusts amplitudes of the first and second signals to generate a first adjusted signal and a second adjusted signal, and a modulator that combines the first and second adjusted signals into the waveform. The amplitudes of the first and second signals may be responsive to predetermined calibration data for the sensor and the monitor.

An aspect of a physiological measurement communications adapter method comprises the steps of inputting a sensor signal at a patient location, communicating patient data derived from the sensor signal between the patient location and a monitor location, constructing a waveform at the monitor location responsive to the sensor signal, and providing the waveform to a monitor via a sensor port. The waveform is constructed so that the monitor calculates a parameter generally equivalent to a measurement derivable from the sensor signal.

In one embodiment, the communicating step may comprise the substeps of deriving a conditioned signal from the sensor signal, calculating a parameter signal from the conditioned signal, and transmitting the parameter signal from the patient location to the monitor location. The constructing step may comprise the substep of synthesizing the waveform from the parameter signal. In an alternative embodiment, the communicating step may comprise the substeps of deriving a conditioned signal from said sensor signal and transmitting the conditioned signal from the patient location to the monitor location. The constructing step may comprise the substeps of demodulating the conditioned signal and remodulating the conditioned signal to generate the waveform. The providing step may comprise the substeps of inputting a monitor signal from an LED drive output of the sensor port, modulating the waveform in response to the monitor signal, and outputting the waveform on a detector input of the sensor port.

Another aspect of a physiological measurement communications adapter comprises a sensor interface means for inputting a sensor signal and outputting a conditioned signal, a transmitter means for sending data responsive to the sensor signal, and a receiver means for receiving the data. The communications adapter further comprises a waveform processor means for constructing a waveform from the data so that measurements derived by a monitor from the waveform are generally equivalent to measurements derivable from the sensor signal, and a monitor interface means for communicating the waveform to a sensor port of the monitor. The communications adapter may further comprise a signal processor means for deriving a parameter signal from the conditioned signal, where the data comprises the parameter signal. The waveform processor means may comprise a means for synthesizing the waveform from the parameter signal. The data may comprise the conditioned signal, and the waveform processor means may comprise a means for modulating the conditioned signal in response to the monitor.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an illustration of a prior art pulse oximetry system;

FIG. **2** is a functional block diagram of a prior art pulse oximetry system;

FIG. **3** is an illustration of a physiological measurement communications adapter;

FIGS. **4**A-B are illustrations of communications adapter sensor modules;

FIGS. **5**A-C are illustrations of communications adapter monitor modules;

FIG. **6** is a functional block diagram of a communications adapter sensor module;

FIG. **7** is a functional block diagram of a communications adapter monitor module;

FIG. **8** is a functional block diagram of a sensor module configured to transmit measured pulse oximeter parameters;

FIG. **9** is a functional block diagram of a monitor module configured to received measured pulse oximeter parameters;

FIG. **10** is a functional block diagram of a sensor module configured to transmit a plethysmograph;

FIG. **11** is a functional block diagram of a monitor module configured to receive a plethysmograph;

FIG. **12** is a functional block diagram of a waveform modulator;

FIG. **13** is a functional block diagram of a sensor module configured for multiple sensors; and

FIG. **14** is a functional block diagram of a monitor module configured for multiple sensors.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Overview

FIG. **3** illustrates one embodiment of a communications adapter. FIGS. **4**-**5** illustrate physical configurations for a communications adapter. In particular, FIGS. **4**A-B illustrate sensor module configurations and FIGS. **5**A-C illustrate monitor module configurations. FIGS. **6**-**14** illustrate communications adapter functions. In particular, FIGS. **6**-**7** illustrate general functions for a sensor module and a monitor module, respectively. FIGS. **8**-**9** functionally illustrate a communications adapter where derived pulse oximetry parameters, such as saturation and pulse rate are transmitted between a sensor module and a monitor module. Also, FIGS. **10**-**12** functionally illustrate a communications adapter where a plethysmograph is transmitted between a sensor module and a monitor module. FIGS. **13**-**14** functionally illustrate a multiple-parameter communications adapter.

FIG. **3** illustrates a communications adapter **300** having a sensor module **400** and a monitor module **500**. The communications adapter **300** communicates patient data derived from a sensor **310** between the sensor module **400**, which is located proximate a patient **20** and the monitor module **500**, which is located proximate a monitor **360**. A wireless link **340** is provided between the sensor module **400** and the monitor module **500**, replacing the conventional patient cable, such as a pulse oximetry patient cable **140** (FIG. **1**). Advantageously, the sensor module **400** is plug-compatible with a conventional sensor **310**. In particular, the sensor connector **318** connects to the sensor module **400** in a similar manner as to a patient cable. Further, the sensor module **400** outputs a drive signal to the sensor **310** and inputs a sensor signal from the sensor **310** in an equivalent manner as a conventional monitor **360**. The sensor module **400** may be battery powered or externally powered. External power may be for recharging internal batteries or for powering the sensor module during operation or both.

As shown in FIG. **3**, the monitor module **500** is advantageously plug-compatible with a conventional monitor **360**. In particular, the monitor's sensor port **362** connects to the monitor module **500** in a similar manner as to a patient cable, such as a pulse oximetry patient cable **140** (FIG. **1**). Further, the monitor module **500** inputs a drive signal from the monitor **360** and outputs a corresponding sensor signal to the monitor **360** in an equivalent manner as a conventional sensor **310**. As such, the combination sensor module **400** and monitor module **500** provide a plug-compatible wireless replacement for a patient cable, adapting an existing wired physiological measurement system into a wireless physiological measurement system. The monitor module **500** may be battery powered, powered from the monitor, such as by tapping current from a monitor's LED drive, or externally powered from an independent AC or DC power source.

Although a communications adapter **300** is described herein with respect to a pulse oximetry sensor and monitor, one of ordinary skill in the art will recognize that a communications adapter may provide a plug-compatible wireless replace for a patient cable that connects any physiological sensor and corresponding monitor. For example, a communications adapter **300** may be applied to a biopotential sensor, a non-invasive blood pressure (NIBP) sensor, a respiratory rate sensor, a glucose sensor and the corresponding monitors, to name a few.

Sensor Module Physical Configurations

FIGS. **4**A-B illustrate physical embodiments of a sensor module **400**. FIG. **4**A illustrates a wrist-mounted module **410** having a wrist strap **411**, a case **412** and an auxiliary cable **420**. The case **412** contains the sensor module electronics, which are functionally described with respect to FIG. **6**, below. The case **412** is mounted to the wrist strap **411**, which attaches the wrist-mounted module **410** to a patient **20**. The auxiliary cable **420** mates to a sensor connector **318** and a module connector **414**, providing a wired link between a conventional sensor **310** and the wrist-mounted module **410**. Alternatively, the auxiliary cable **420** is directly wired to the sensor module **400**. The wrist-mounted module **410** may have a display **415** that shows sensor measurements, module status and other visual indicators, such as monitor status. The wrist-mounted module **410** may also have keys (not shown) or other input mechanisms to control its operational mode and characteristics. In an alternative embodiment, the sensor **310** may have a tail (not shown) that connects directly to the wrist-mounted module **410**, eliminating the auxiliary cable **420**.

FIG. **4**B illustrates a clip-on module **460** having a clip **461**, a case **462** and an auxiliary cable **470**. The clip **461** attaches the clip-on module **460** to patient clothing or objects near a patient **20**, such as a bed frame. The auxiliary cable **470** mates to the sensor connector **318** and functions as for the auxiliary cable **420** (FIG. **4**A) of the wrist-mounted module **410** (FIG. **4**A), described above. The clip-on module **460** may have a display **463** and keys **464** as for the wrist-mounted module **410** (FIG. **4**A). Either the wrist-mounted module **410** or the clip-on module **460** may have other input or output ports (not shown) that download software, configure the module, or provide a wired connection to other measurement instruments or computing devices, to name a few examples.

Monitor Module Physical Configurations

FIGS. **5**A-C illustrate physical embodiments of a monitor module **500**. FIG. **5**A illustrates a direct-connect module **510** having a case **512** and an integrated monitor connector **514**. The case **512** contains the monitor module electronics, which are functionally described with respect to FIG. **7**, below. The monitor connector **514** mimics that of the monitor end of a patient cable, such as a pulse oximetry patient cable **140** (FIG. **1**), and electrically and mechanically connects the monitor module **510** to the monitor **360** via the monitor's sensor port **362**.

FIG. **5**B illustrates a cable-connect module **540** having a case **542** and an auxiliary cable **550**. The case **542** functions as for the direct-connect module **510** (FIG. **5**A), described above. Instead of directly plugging into the monitor **360**, the cable-connect module **540** utilizes the auxiliary cable **550**, which mimics the monitor end of a patient cable, such as a pulse oximetry patient cable **140** (FIG. **1**), and electrically connects the cable-connect module **540** to the monitor sensor port **362**.

FIG. **5**C illustrates a plug-in module **570** having a plug-in case **572** and an auxiliary cable **580**. The plug-in case **572** is mechanically compatible with the plug-in chassis of a multiparameter monitor **370** and may or may not electrically connect to the chassis backplane. The auxiliary cable **580** mimics a patient cable and electrically connects the plug-in module **570** to the sensor port **372** of another plug-in device. A direct-connect module **510** (FIG. **5**A) or a cable-connect module **540** (FIG. **5**B) may also be used with a multiparameter monitor **370**.

In a multiparameter embodiment, such as described with respect to FIGS. **13-14**, below, a monitor module **500** may connect to multiple plug-in devices of a multiparameter monitor **370**. For example, a cable-connect module **540** (FIG. **5**B) may have multiple auxiliary cables **550** (FIG. **5**B) that connect to multiple plug-in devices installed within a multiparameter monitor chassis. Similarly, a plug-in module **570** may have one or more auxiliary cables **580** with multiple connectors for attaching to the sensor ports **372** of multiple plug-in devices.

Communications Adapter Functions

FIGS. **6-7** illustrate functional embodiments of a communications adapter. FIG. **6** illustrates a sensor module **400** having a sensor interface **610**, a signal processor **630**, an encoder **640**, a transmitter **650** and a transmitting antenna **670**. A physiological sensor **310** provides an input sensor signal **612** at the sensor connector **318**. Depending on the sensor **310**, the sensor module **400** may provide one or more drive signals **618** to the sensor **310**. The sensor interface **610** inputs the sensor signal **612** and outputs a conditioned signal **614**. The conditioned signal **614** may be coupled to the transmitter **650** or further processed by a signal processor **630**. If the sensor module configuration utilizes a signal processor **630**, it derives a parameter signal **632** responsive to the sensor signal **612**, which is then coupled to the transmitter **650**. Regardless, the transmitter **650** inputs a baseband signal **642** that is responsive to the sensor signal **612**. The transmitter **650** modulates the baseband signal **642** with a carrier to generate a transmit signal **654**. The transmit signal **654** may be derived by various amplitude, frequency or phase modulation schemes, as is well known in the art. The transmit signal **654** is coupled to the transmit antenna **670**, which provides wireless communications to a corresponding receive antenna **770** (FIG. **7**), as described below.

As shown in FIG. **6**, the sensor interface **610** conditions and digitizes the sensor signal **612** to generate the conditioned signal **614**. Sensor signal conditioning may be performed in the analog domain or digital domain or both and may include amplification and filtering in the analog domain and filtering, buffering and data rate modification in the digital domain, to name a few. The resulting conditioned signal **614** is responsive to the sensor signal **612** and may be used to calculate or derive a parameter signal **632**.

Further shown in FIG. **6**, the signal processor **630** performs signal processing on the conditioned signal **614** to generate the parameter signal **632**. The signal processing may include buffering, digital filtering, smoothing, averaging, adaptive filtering and frequency transforms to name a few. The resulting parameter signal **632** may be a measurement calculated or derived from the conditioned signal, such as oxygen saturation, pulse rate, blood glucose, blood pressure and EKG to name a few. Also, the parameter signal **632** may be an intermediate result from which the above-stated measurements may be calculated or derived.

As described above, the sensor interface **610** performs mixed analog and digital pre-processing of an analog sensor signal and provides a digital output signal to the signal processor **630**. The signal processor **630** then performs digital post-processing of the front-end processor output. In alternative embodiments, the input sensor signal **612** and the output conditioned signal **614** may be either analog or digital, the front-end processing may be purely analog or purely digital, and the back-end processing may be purely analog or mixed analog or digital.

In addition, FIG. **6** shows an encoder **640**, which translates a digital word or serial bit stream, for example, into the baseband signal **642**, as is well-known in the art. The baseband signal **642** comprises the symbol stream that drives the transmit signal **654** modulation, and may be a single signal or multiple related signal components, such as in-phase and quadrature signals. The encoder **640** may include data compression and redundancy, also well-known in the art.

FIG. **7** illustrates a monitor module **500** having a receive antenna **770**, a receiver **710**, a decoder **720**, a waveform processor **730** and a monitor interface **750**. A receive signal **712** is coupled from the receive antenna **770**, which provides wireless communications to a corresponding transmit antenna **670** (FIG. **6**), as described above. The receiver **710** inputs the receive signal **712**, which corresponds to the transmit signal **654** (FIG. **6**). The receiver **710** demodulates the receive signal to generate a baseband signal **714**. The decoder **720** translates the symbols of the demodulated baseband signal **714** into a decoded signal **724**, such as a digital word stream or bit stream. The waveform processor **730** inputs the decoded signal **724** and generates a constructed signal **732**. The monitor interface **750** is configured to communicate the constructed signal **732** to a sensor port **362** of a monitor **360**. The monitor **360** may output a sensor drive signal **754**, which the monitor interface **750** inputs to the waveform processor **730** as a monitor drive signal **734**. The waveform processor **730** may utilize the monitor drive signal **734** to generate the constructed signal **732**. The monitor interface **750** may also provide characterization information **758** to the waveform processor **730**, relating to the monitor **360**, the sensor **310** or both, that the waveform processor **730** utilizes to generate the constructed signal **732**.

The constructed signal **732** is adapted to the monitor **360** so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent to measurements derivable from the sensor signal **612** (FIG. **6**). Note that the sensor **310** (FIG. **6**) may or may not be directly compatible with the monitor **360**. If the sensor **310** (FIG. **6**) is compatible with the monitor **360**, the constructed signal **732** is generated so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent (within clinical significance) with those derivable directly from the sensor signal **612** (FIG. **6**). If the sensor **310** (FIG. **6**) is not compatible with the monitor **360**, the constructed signal **732** is generated so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent to those derivable directly from the sensor signal **612** (FIG. **6**) using a compatible monitor.

Wireless Pulse Oximetry

FIGS. **8-11** illustrate pulse oximeter embodiments of a communications adapter. FIGS. **8-9** illustrate a sensor module and a monitor module, respectively, configured to communicate measured pulse oximeter parameters. FIG. **10-11** illustrate a sensor module and a monitor module, respectively, configured to communicate a plethysmograph signal.

Parameter Transmission

FIG. **8** illustrates a pulse oximetry sensor module **800** having a sensor interface **810**, signal processor **830**, encoder **840**, transmitter **850**, transmitting antenna **870** and controller **890**. The sensor interface **810**, signal processor **830** and controller **890** function as described with respect to FIG. **2**, above. The sensor interface **810** communicates with a standard pulse oximetry sensor **310**, providing an LED drive signal **818** to the LED emitters **312** and receiving a sensor signal **812** from the detector **314** in response. The sensor interface **810** provides front-end processing of the sensor signal **812**, also described above, providing a plethysmograph signal **814** to the signal processor **830**. The signal processor **830** then derives a parameter signal **832** that comprises a real time measurement of oxygen saturation and pulse rate. The parameter signal **832** may include other parameters, such as measurements of perfusion index and signal quality. In one embodiment, the signal processor is an MS-5 or MS-7 board available from Masimo Corporation, Irvine, Calif.

As shown in FIG. **8**, the encoder **840**, the transmitter **850** and the transmitting antenna **870** function as described with respect to FIG. **6**, above. For example, the parameter signal **832** may be a digital word stream that is serialized into a bit stream and encoded into a baseband signal **842**. The baseband signal **842** may be, for example, two bit symbols that drive a quadrature phase shift keyed (QPSK) modulator in the transmitter **850**. Other encodings and modulations are also applicable, as described above. The transmitter **850** inputs the baseband signal **842** and generates a transmit signal **854** that is a modulated carrier having a frequency suitable for short-range transmission, such as within a hospital room, doctor's office, emergency vehicle or critical care ward, to name a few. The transmit signal **854** is coupled to the transmit antenna **870**, which provides wireless communications to a corresponding receive antenna **970** (FIG. **9**), as described below.

FIG. **9** illustrates a monitor module **900** having a receive antenna **970**, a receiver **910**, a decoder **920**, a waveform generator **930** and an interface cable **950**. The receive antenna **970**, receiver **910** and decoder **920** function as described with respect to FIG. **7**, above. In particular, the receive signal **912** is coupled from the receive antenna **970**, which provides wireless communications to a corresponding transmit antenna **870** (FIG. **8**). The receiver **910** inputs the receive signal **912**, which corresponds to the transmit signal **854** (FIG. **8**). The receiver **810** demodulates the receive signal **912** to generate a baseband signal **914**. Not accounting for transmission errors, the baseband signal **914** corresponds to the sensor module baseband signal **842** (FIG. **8**), for example a symbol stream of two bits each. The decoder **920** assembles the baseband signal **914** into a parameter signal **924**, which, for example, may be a sequence of digital words corresponding to oxygen saturation and pulse rate.

Again, not accounting for transmission errors, the monitor module parameter signal **924** corresponds to the sensor module parameter signal **832** (FIG. **8**), derived by the signal processor **830** (FIG. **8**).

Also shown in FIG. **9**, the waveform generator **930** is a particular embodiment of the waveform processor **730** (FIG. **7**) described above. The waveform generator **930** generates a synthesized waveform **932** that the pulse oximeter monitor **360** can process to calculate SpO_2 and pulse rate values or exception messages. In the present embodiment, the waveform generator output does not reflect a physiological waveform. In particular, the synthesized waveform is not physiological data from the sensor module **800**, but is a waveform synthesized from predetermined stored waveform data to cause the monitor **360** to calculate oxygen saturation and pulse rate equivalent to or generally equivalent (within clinical significance) to that calculated by the signal processor **830** (FIG. **8**). The actual intensity signal from the patient received by the detector **314** (FIG. **8**) is not provided to the monitor **360** in the present embodiment. Indeed, the waveform provided to the monitor **360** will usually not resemble a plethysmographic waveform or other physiological data from the patient to whom the sensor module **800** (FIG. **8**) is attached.

The synthesized waveform **932** is modulated according to the drive signal input **934**. That is, the pulse oximeter monitor **360** expects to receive a red and IR modulated intensity signal originating from a detector, as described with respect to FIGS. **1**-**2**, above. The waveform generator **930** generates the synthesized waveform **932** with a predetermined shape, such as a triangular or sawtooth waveform stored in waveform generator memory or derived by a waveform generator algorithm. The waveform is modulated synchronously with the drive input **934** with first and second amplitudes that are processed in the monitor **360** as red and IR portions of a sensor signal. The frequency and the first and second amplitudes are adjusted so that pulse rate and oxygen saturation measurements derived by the pulse oximeter monitor **360** are generally equivalent to the parameter measurements derived by the signal processor **830** (FIG. **8**), as described above. One embodiment of a waveform generator **930** is described in U.S. Patent Application No. 60/117,097 entitled "Universal/Upgrading Pulse Oximeter," assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein. Although the waveform generator **930** is described above as synthesizing a waveform that does not resemble a physiological signal, one of ordinary skill will recognize that another embodiment of the waveform generator **930** could incorporate, for example, a plethysmograph simulator or other physiological signal simulator.

Further shown in FIG. **9**, the interface cable **950** functions in a manner similar to the monitor interface **750** (FIG. **7**) described above. The interface cable **950** is configured to communicate the synthesized waveform **932** to the monitor **360** sensor port and to communicate the sensor drive signal **934** to the waveform generator **930**. The interface cable **950** may include a ROM **960** that contains monitor and sensor characterization data. The ROM **960** is read by the waveform generator **930** so that the synthesized waveform **932** is adapted to a particular monitor **360**. For example, the ROM **960** may contain calibration data of red/IR versus oxygen saturation, waveform amplitude and waveform shape information. An interface cable is described in U.S. Patent Application No. 60/117,092, referenced above. Monitor-specific SatShare™ brand interface cables are available from Masimo Corporation, Irvine, Calif. In an alternative embodiment, such as a direct connect monitor module as illustrated in FIG. **5**A, an interface cable **950** is not used and the ROM **960** may be incorporated within the monitor module **900** itself.

Plethysmograph Transmission

FIG. **10** illustrates another pulse oximetry sensor module **1000** having a sensor interface **1010**, encoder **1040**, transmitter **1050**, transmitting antenna **1070** and controller **1090**, which have the corresponding functions as those described with respect to FIG. **8**, above. The encoder **1040**, however, inputs a plethysmograph signal **1014** rather than oxygen saturation and pulse rate measurements **832** (FIG. **8**). Thus, the sensor module **1000** according to this embodiment encodes and transmits a plethysmograph signal **1014** to a corresponding monitor module **1100** (FIG. **11**) in contrast to derived physiological parameters, such as oxygen saturation and pulse rate. The plethysmograph signal **1014** is illustrated in FIG. **10** as being a direct output from the sensor interface **1010**. In another embodiment, the sensor module **1000** incorporates a decimation processor, not shown, after the sensor interface **1010** so as to provide a plethysmograph signal **1014** having a reduced sample rate.

FIG. **11** illustrates another pulse oximetry monitor module **1100** having a receive antenna **1170**, a receiver **1110**, a decoder **1120** and an interface cable **1150**, which have the corresponding functions as those described with respect to FIG. **9**, above. This monitor module embodiment **1100**, however, has a waveform modulator **1200** rather than a waveform generator **930** (FIG. **9**), as described above. The waveform modulator **1200** inputs a plethysmograph signal from the decoder **1120** rather than oxygen saturation and pulse rate measurements, as described with respect to FIG. **9**, above. Further, the waveform modulator **1200** provides an modulated waveform **1132** to the pulse oximeter monitor **360** rather than a synthesized waveform, as described with respect to FIG. **9**. The modulated waveform **1132** is a plethysmographic waveform modulated according to the monitor drive signal input **1134**. That is, the waveform modulator **1200** does not synthesize a waveform, but rather modifies the received plethysmograph signal **1124** to cause the monitor **360** to calculate oxygen saturation and pulse rate generally equivalent (within clinical significance) to that derivable by a compatible, calibrated pulse oximeter directly from the sensor signal **1012** (FIG. **10**). The waveform modulator **1200** is described in further detail with respect to FIG. **12**, below.

FIG. **12** shows a waveform modulator **1200** having a demodulator **1210**, a red digital-to-analog converter (DAC) **1220**, an IR DAC **1230**, a red amplifier **1240**, an IR amplifier **1250**, a modulator **1260**, a modulator control **1270**, a look-up table (LUT) **1280** and a ratio calculator **1290**. The waveform modulator **1200** demodulates red and IR plethysmographs ("pleths") from the decoder output **1124** into a separate red pleth **1222** and IR pleth **1232**. The waveform modulator **1200** also adjusts the amplitudes of the pleths **1222**, **1232** according to stored calibration curves for the sensor **310** (FIG. **10**) and the monitor **360** (FIG. **11**). Further, the waveform modulator **1200** re-modulates the adjusted red pleth **1242** and adjusted IR pleth **1252**, generating a modulated waveform **1132** to the monitor **360** (FIG. **11**).

As shown in FIG. **12**, the demodulator **1210** performs the demodulation function described above, generating digital red and IR pleth signals **1212**, **1214**. The DACs **1220**, **1230** convert the digital pleth signals **1212**, **1214** to corresponding analog pleth signals **1222**, **1232**. The amplifiers **1240**, **1250** have variable gain control inputs **1262**, **1264** and perform the amplitude adjustment function described above, gener-

ating adjusted red and IR pleth signals **1242**, **1252**. The modulator **1260** performs the re-modulation function described above, combining the adjusted red and IR pleth signals **1242**, **1252** according to a control signal **1272**. The modulator control **1270** generates the control signal **1272** synchronously with the LED drive signal(s) **1134** from the monitor **360**.

Also shown in FIG. **12**, the ratio calculator **1290** derives a red/IR ratio from the demodulator outputs **1212**, **1214**. The LUT **1280** stores empirical calibration data for the sensor **310** (FIG. **10**). The LUT **1280** also downloads monitor-specific calibration data from the ROM **1160** (FIG. **11**) via the ROM output **1158**. From this calibration data, the LUT **1280** determines a desired red/IR ratio for the modulated waveform **1132** and generates red and IR gain outputs **1262**, **1264** to the corresponding amplifiers **1240**, **1250**, accordingly. A desired red/IR ratio is one that allows the monitor **360** (FIG. **11**) to derive oxygen saturation measurements from the modulated waveform **1132** that are generally equivalent to that derivable directly from the sensor signal **1012** (FIG. **10**).

One of ordinary skill in the art will recognize that some of the signal processing functions described with respect to FIGS. **8-11** may be performed either within a sensor module or within a monitor module. Signal processing functions performed within a sensor module may advantageously reduce the transmission bandwidth to a monitor module at a cost of increased sensor module size and power consumption. Likewise, signal processing functions performed within a monitor module may reduce sensor module size and power consumption at a cost of increase transmission bandwidth.

For example, a monitor module embodiment **900** (FIG. **9**) described above receives measured pulse oximeter parameters, such as oxygen saturation and pulse rate, and generates a corresponding synthesized waveform. In that embodiment, the oxygen saturation and pulse rate computations are performed within a sensor module **800** (FIG. **8**). Another monitor module embodiment **1100** (FIG. **11**), also described above, receives a plethysmograph waveform and generates a remodulated waveform. In that embodiment, minimal signal processing is performed within a sensor module **1000** (FIG. **10**). In yet another embodiment, not shown, a sensor module transmits a plethysmograph waveform or a decimated plethysmograph waveform having a reduced sample rate. A corresponding monitor module has a signal processor, such as described with respect to FIG. **8**, in addition to a waveform generator, as described with respect to FIG. **9**. The signal processor computes pulse oximeter parameters and the waveform generator generates a corresponding synthesized waveform, as described above. In this embodiment, minimal signal processing is performed within the sensor module, and the monitor module functions are performed on the pulse oximeter parameters computed within the monitor module.

Wireless Multiple Parameter Measurements

FIGS. **13-14** illustrate a multiple parameter communications adapter. FIG. **13** illustrates a multiple parameter sensor module **1300** having sensor interfaces **1310**, one or more signal processors **1330**, a multiplexer and encoder **1340**, a transmitter **1350**, a transmitting antenna **1370** and a controller **1390**. One or more physiological sensors **1301** provide input sensor signals **1312** to the sensor module **1300**. Depending on the particular sensors **1301**, the sensor module **1300** may provide one or more drive signals **1312** to the sensors **1301** as determined by the controller **1390**. The sensor interfaces **1310** input the sensor signals **1312** and output one or more conditioned signals **1314**. The conditioned signals **1314** may be coupled to the transmitter **1350** or further processed by the signal processors **1330**. If the sensor module configuration utilizes signal processors **1330**, it derives multiple parameter signals **1332** responsive to the sensor signals **1312**, which are then coupled to the transmitter **1350**. Regardless, the transmitter **1350** inputs a baseband signal **1342** that is responsive to the sensor signals **1312**. The transmitter **1350** modulates the baseband signal **1342** with a carrier to generate a transmit signal **1354**, which is coupled to the transmit antenna **1370** and communicated to a corresponding receive antenna **1470** (FIG. **14**), as described with respect to FIG. **6**, above. Alternatively, there may be multiple baseband signals **1342**, and the transmitter **1350** may transmit on multiple frequency channels, where each channel coveys data responsive to one or more of the sensor signals **1314**.

As shown in FIG. **13**, the sensor interface **1310** conditions and digitizes the sensor signals **1312** as described for a single sensor with respect to FIG. **6**, above. The resulting conditioned signals **1314** are responsive to the sensor signals **1312**. The signal processors **1330** perform signal processing on the conditioned signals **1314** to derive parameter signals **1332**, as described for a single conditioned signal with respect to FIG. **6**, above. The parameter signals **1332** may be physiological measurements such as oxygen saturation, pulse rate, blood glucose, blood pressure, EKG, respiration rate and body temperature to name a few, or may be intermediate results from which the above-stated measurements may be calculated or derived. The multiplexer and encoder **1340** combines multiple digital word or serial bit streams into a single digital word or bit stream. The multiplexer and encoder also encodes the digital word or bit stream to generate the baseband signal **1342**, as described with respect to FIG. **6**, above.

FIG. **14** illustrates a multiple parameter monitor module **1400** having a receive antenna **1470**, a receiver **1410**, a demultiplexer and decoder **1420**, one or more waveform processors **1430** and a monitor interface **1450**. The receiver **1410** inputs and demodulates the receive signal **1412** corresponding to the transmit signal **1354** (FIG. **13**) to generate a baseband signal **1414** as described with respect to FIG. **7**, above. The demultiplexer and decoder **1420** separates the symbol streams corresponding to the multiple conditioned signals **1314** (FIG. **13**) and/or parameter signals **1332** (FIG. **13**) and translates these symbol streams into multiple decoded signals **1422**, as described for a single symbol stream with respect to FIG. **7**, above. Alternatively, multiple frequency channels are received to generate multiple baseband signals, each of which are decoded to yield multiple decoded signals **1422**. The waveform processors **1430** input the decoded signals **1422** and generate multiple constructed signals **1432**, as described for a single decoded signal with respect to FIGS. **7-12**, above. The monitor interface **1450** is configured to communicate the constructed signals **1432** to the sensor ports of a multiple parameter monitor **1401** or multiple single parameter monitors, in a manner similar to that for a single constructed signal, as described with respect to FIGS. **7-12**, above. In particular, the constructed signals **1432** are adapted to the monitor **1401** so that measurements derived by the monitor **1401** from the constructed signals **1432** are generally equivalent to measurements derivable directly from the sensor signals **1312** (FIG. **13**).

A physiological measurement communications adapter is described above with respect to wireless communications and, in particular, radio frequency communications. A sensor module and monitor module, however, may also communi-

cate via wired communications, such as telephone, Internet or fiberoptic cable to name a few. Further, wireless communications can also utilize light frequencies, such as IR or laser to name a few.

A physiological measurement communications adapter has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only. One of ordinary skill in the art will appreciate many variations and modifications of a physiological measurement communications adapter within the scope of the claims that follow.

What is claimed is:

1. A body worn mobile medical monitoring device configured to minimize cable wiring from a sensor by placement of one or more sensor communication ports, the mobile medical monitoring device comprising:

a housing configured to be secured on a lower arm of a patient being monitored via a strap extending around the lower arm of the patient;

a display positioned on a face of the housing, opposite the strap, so as to be visible to a user;

a first sensor communication port positioned on a side of the housing and configured to face a hand of the lower arm of the patient when the mobile medical monitoring device is mounted to the lower arm of the patient, wherein:

the side of the housing faces the hand of the lower arm of the patient of the patient when the mobile medical monitoring device is mounted to the lower arm of the patient,

the first sensor communication port is configured to provide wired communication with a pulse oximetry sensor attached to a digit of the hand of the patient,

the wired communication with the pulse oximetry sensor provided at least partly in the analog domain, and

the first sensor communication port is positioned on the side of the housing such that a path from the first sensor communication port on the side of the housing to the digit of the patient is substantially perpendicular to the side of the housing and shorter than any other path from any other side of the housing to the digit of the patient;

a plurality of additional sensor communications ports positioned on the housing and configured to provide wired communication with a plurality of additional physiological sensors at least partly in the digital domain; and

one or more processors and a transmitter configured to:

display, on the display, physiological measurements derived from the pulse oximetry sensor and the plurality of additional physiological sensors; and

wirelessly transmit information indicative of the physiological measurements to a remote computing device.

2. The mobile medical monitoring device of claim **1**, wherein the wired communication with the pulse oximetry sensor is provided via a tail extending from the pulse oximetry sensor.

3. The mobile medical monitoring device of claim **2**, wherein the tail comprises a cable that is configured to be removably attachable to the first sensor communication port.

4. The mobile medical monitoring device of claim **3**, wherein a length of the cable corresponds to the path from the sensor communication port on the side of the housing to the digit of the patient.

5. The mobile medical monitoring device of claim **3**, wherein the cable is appropriately sized based on the path from the sensor communication port on the side of the housing to the digit of the patient.

6. The mobile medical monitoring device of claim **3**, wherein the path from the sensor communication port on the side of the housing to the digit of the patient runs at least partly along a backside of the hand of the patient.

7. The mobile medical monitoring device of claim **1**, wherein the face of the housing comprises a single user interface.

8. The mobile medical monitoring device of claim **7**, wherein the single user interface comprises the display.

9. The mobile medical monitoring device of claim **8**, wherein:

the housing comprises a back side that is opposite the face of the housing,

the strap is mountable to the back side of the housing, and

the face of the housing is raised from the strap and the lower arm of the patient to enable positioning of the first sensor communication port on the side of the housing between the lower arm of the patient and the face of the housing.

10. The mobile medical monitoring device of claim **9**, wherein:

the front side of the housing comprises a bezel and the display, and

a top of the first sensor communication port is located below the face of the housing.

11. The mobile medical monitoring device of claim **10**, wherein the display is positioned centrally on the face of the housing.

12. The mobile medical monitoring device of claim **11**, wherein the display positioned on the face of the housing is sized such that the display covers most of a length of a shortest dimension of the face of the housing.

13. A body worn, battery-powered medical monitoring device configured to provide on-patient and remote monitoring of patient physiological parameters, the medical monitoring device comprising:

a battery configured to provide power to the medical monitoring device such that the medical monitoring device may operate without a wired power connection;

a case configured to house the battery;

a strap configured to attach the case to an arm of a patient and be mountable to the case;

a first communications port positioned on a face of a side of the case configured to be nearest to a hand of the arm of the patient when the case is mounted to the arm of the patient, the first communications port configured to removably couple with a cable of a finger- or thumb-type pulse oximetry sensor and positioned on the face of the side of the case to provide a path from the first communications port to a digit of the hand of the patient that avoids tangling of the cable, the first communications port configured such that the cable perpendicularly extends from the face of the side of the case when the cable is coupled to the first communications port;

a second communications port configured to provide wired communications with a second physiological sensor arrangement at least partly via digital communications;

a third communications port configured to provide wired communications with a third physiological sensor arrangement;

a display configured to provide real time measurements of patient physiological parameters based at least in part on data obtained from at least the pulse oximetry sensor via the first communications port; and

a transmitter configured to wirelessly transmit information indicative of real time measurements of patient physiological parameters based at least in part on data obtained from the pulse oximetry sensor via the first communications port.

14. The medical monitoring device of claim **13**, wherein the path from the first communications port to a digit of the hand is shorter than any path from any communications port located on any other side of the case to the digit of the hand.

15. The medical monitoring device of claim **13** further comprising:

one or more hardware processors configured to:

process the data obtained from the pulse oximetry sensor; and

determine, based at least in part on the data, the real time measurements of patient physiological parameters.

16. The medical monitoring device of claim **15**, wherein:

the one or more hardware processors are further configured to:

receive additional data from at least the second physiological sensor arrangement and the third physiological sensor arrangement;

determine, based at least in part on the additional data, real time measurements of additional patient physiological parameters; and

cause to be displayed, on the display, the real time measurements of additional patient physiological parameters; and

the transmitter is further configured to:

wirelessly transmit information indicative of real time measurements of additional patient physiological parameters based at least in part on the additional data.

17. The medical monitoring device of claim **16**, wherein the display is positioned on a front, user-facing side of the case to enable a user to view the real time measurements of patient physiological parameters and the real time measurements of additional patient physiological parameters.

18. The medical monitoring device of claim **17**, wherein the second physiological sensor arrangement comprises an EKG sensor arrangement and the third physiological sensor arrangement comprises a blood pressure sensor arrangement.

19. The medical monitoring device of claim **18**, wherein:

the first, second, and third communication ports are communicatively coupled to respective first, second, and third sensor interfaces; and

the first, second, and third sensor interfaces are uniquely configured to receive signals from the respective pulse oximetry sensor, EKG sensor arrangement, and blood pressure sensor arrangement.

20. A body worn portable patient monitoring device configured to provide on-patient and remote monitoring of patient physiological parameters, the portable patient monitoring device comprising:

a pulse oximetry sensor configured to be wrapped around a digit of a patient, the pulse oximetry sensor including at least:

a light emitter configured to emit light into a tissue site of the digit of the patient;

a light detector configured output a first signal responsive to at least a portion of the emitted light after attenuation by tissue of the tissue site; and

a cable extending from the pulse oximetry sensor and configured to electrically convey the first signal;

a blood pressure sensor configured to output a second signal responsive to at least a blood pressure parameter of the patient;

an additional sensor arrangement configured to output a third signal responsive to at least one additional physiological parameter of the patient other than blood pressure or oxygen saturation, the at least one additional physiological parameter including at least one of: temperature or respiration rate;

a housing configured to be secured to a lower arm of the patient, the housing having a size and shape configured to be secured to the lower arm of the patient;

a strap mountable to the back side of the housing, the strap configured to secure the housing to the lower arm of the patient;

a display positioned on a front side of the housing that is opposite a back side of the housing, the display configured to show a status of the portable patient monitoring device and one or more parameter measurements so as to be viewable by a user, wherein the display is positioned centrally on the front side of the display and is sized such that the display spans most of a length of a shortest dimension of the front side of the housing, and wherein the front side of the housing comprises a single user interface and a bezel;

one or more user input mechanisms configured to control an operational mode of the portable patient monitoring device in response to inputs from a user;

a first sensor port positioned on a face of a first side of the housing, wherein:

the face of the first side of the housing is configured to face toward a hand having the digit of the patient under measurement when the housing is secured to the lower arm of the patient,

the first sensor port is configured to removably physically couple with the pulse oximetry sensor via the cable and to electrically receive the first signal from the pulse oximetry sensor,

the cable is configured to run from the first sensor port, at least part way along a path substantially perpendicular to the face of the first side of the housing, down the arm of the patient, and to the digit of the patient to which the pulse oximetry sensor is configured to be wrapped around,

the front side of the housing is raised from the strap and the lower arm of the patient to enable positioning of the first sensor port on the first side of the housing between the lower arm of the patient and the front side of the housing, and

a top of the first sensor port is located below the front of the housing;

a second sensor port positioned on the housing and configured to provide wired electrical communication with the blood pressure sensor arrangement and to electrically receive second signal from the blood pressure sensor arrangement;

a third sensor port positioned on the housing and configured to provide electrical wired communication with the additional sensor arrangement and to electrically receive the third signal from the additional sensor arrangement;

a rechargeable battery positioned within the housing and configured to power the portable patient monitoring device such that the portable patient monitoring device is portable and wearable by the patient;

one or more signal processing arrangements positioned within the housing and configured to:

receive the first signal from the pulse oximetry sensor via one or more sensor interfaces, wherein the first signal is provided at least partly as an analog signal;

process the first signal from the pulse oximetry sensor to determine measurements of oxygen saturation and pulse rate;

receive the second signal from the blood pressure sensor arrangement via the one or more sensor interfaces, the second signal responsive to at least a blood pressure parameter of the patient;

receive the third signal from the additional sensor arrangement via the one or more sensor interfaces, the third signal responsive to the at least one additional physiological parameter of the patient including at least one of: temperature or respiration rate, wherein the third signal is provided at least partly as a digital signal; and

cause the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter to all be displayed on the display of the portable patient monitoring device; and

a transmitter positioned within the housing and configured to:

wirelessly transmit a transmit signal including the information indicating the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter to a separate computing device configured to display, on a remote display, the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter.

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US009795300B2

(12) **United States Patent**
Al-Ali

(10) **Patent No.: US 9,795,300 B2**
(45) **Date of Patent: *Oct. 24, 2017**

(54) **WEARABLE PORTABLE PATIENT MONITOR**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/499,716**

(22) Filed: **Apr. 27, 2017**

(65) **Prior Publication Data**

US 2017/0224216 A1 Aug. 10, 2017

Related U.S. Application Data

(63) Continuation of application No. 15/448,989, filed on Mar. 3, 2017, which is a continuation of application
(Continued)

(51) **Int. Cl.**
A61B 5/1455 (2006.01)
A61B 5/0205 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/0024*** (2013.01); ***A61B 5/021*** (2013.01); ***A61B 5/0205*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC ... A61B 5/0002; A61B 5/0004; A61B 5/0024; A61B 5/02; A61B 5/0205; A61B 5/0402;
(Continued)

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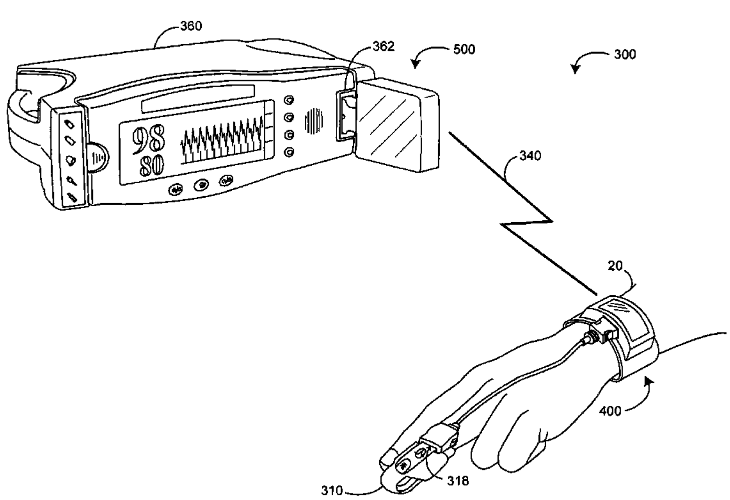
(57) **ABSTRACT**

A wearable, portable physiological monitor configured to wirelessly transmit real time information regarding a plurality physiological parameters. The portable monitor includes a plurality of sensor ports, where at least a first sensor port is positioned on a side of a housing of the portable monitor such that, when the portable monitor is attached to an arm of a patient, a wired connection extending from the first sensor port to a first physiological sensor positioned on a digit of the patient follows a path to the digit of the patient that avoids tangling of the wired connection. The portable monitor further includes one or more processing devices configured to cause display of parameter values, combine information indicative of the signals into a single word or bit stream, and encode and generate a baseband signal. Further includes a transmitter to modulate the baseband signal and wirelessly transmit.

20 Claims, 17 Drawing Sheets



Related U.S. Application Data

No. 14/815,232, filed on Jul. 31, 2015, now abandoned, which is a continuation of application No. 14/217,788, filed on Mar. 18, 2014, now Pat. No. 9,113,832, which is a continuation of application No. 14/037,137, filed on Sep. 25, 2013, now Pat. No. 9,113,831, which is a continuation of application No. 12/955,826, filed on Nov. 29, 2010, now Pat. No. 8,548,548, which is a continuation of application No. 11/417,006, filed on May 3, 2006, now Pat. No. 7,844,315, which is a continuation of application No. 11/048,330, filed on Feb. 1, 2005, now Pat. No. 7,844,314, which is a continuation of application No. 10/377,933, filed on Feb. 28, 2003, now Pat. No. 6,850,788.

(60) Provisional application No. 60/367,428, filed on Mar. 25, 2002.

(51) **Int. Cl.**

A61B 5/00	(2006.01)
A61B 5/021	(2006.01)
A61B 5/0428	(2006.01)
G08B 21/04	(2006.01)
H04W 4/00	(2009.01)

(52) **U.S. Cl.**
CPC ***A61B 5/0428*** (2013.01); ***A61B 5/14552*** (2013.01); ***A61B 5/6824*** (2013.01); ***A61B 5/6831*** (2013.01); ***A61B 5/7228*** (2013.01); ***A61B 5/7425*** (2013.01); ***A61B 5/7445*** (2013.01); ***A61B 5/7475*** (2013.01); ***G08B 21/0453*** (2013.01); *A61B 2562/222* (2013.01); *A61B 2562/227* (2013.01); *H04W 4/005* (2013.01)

(58) **Field of Classification Search**
CPC . A61B 5/1455; A61B 5/14551; A61B 5/6825; A61B 5/6826; A61B 5/6831; A61B 5/72; A61B 2560/0043; A61B 2562/06
See application file for complete search history.

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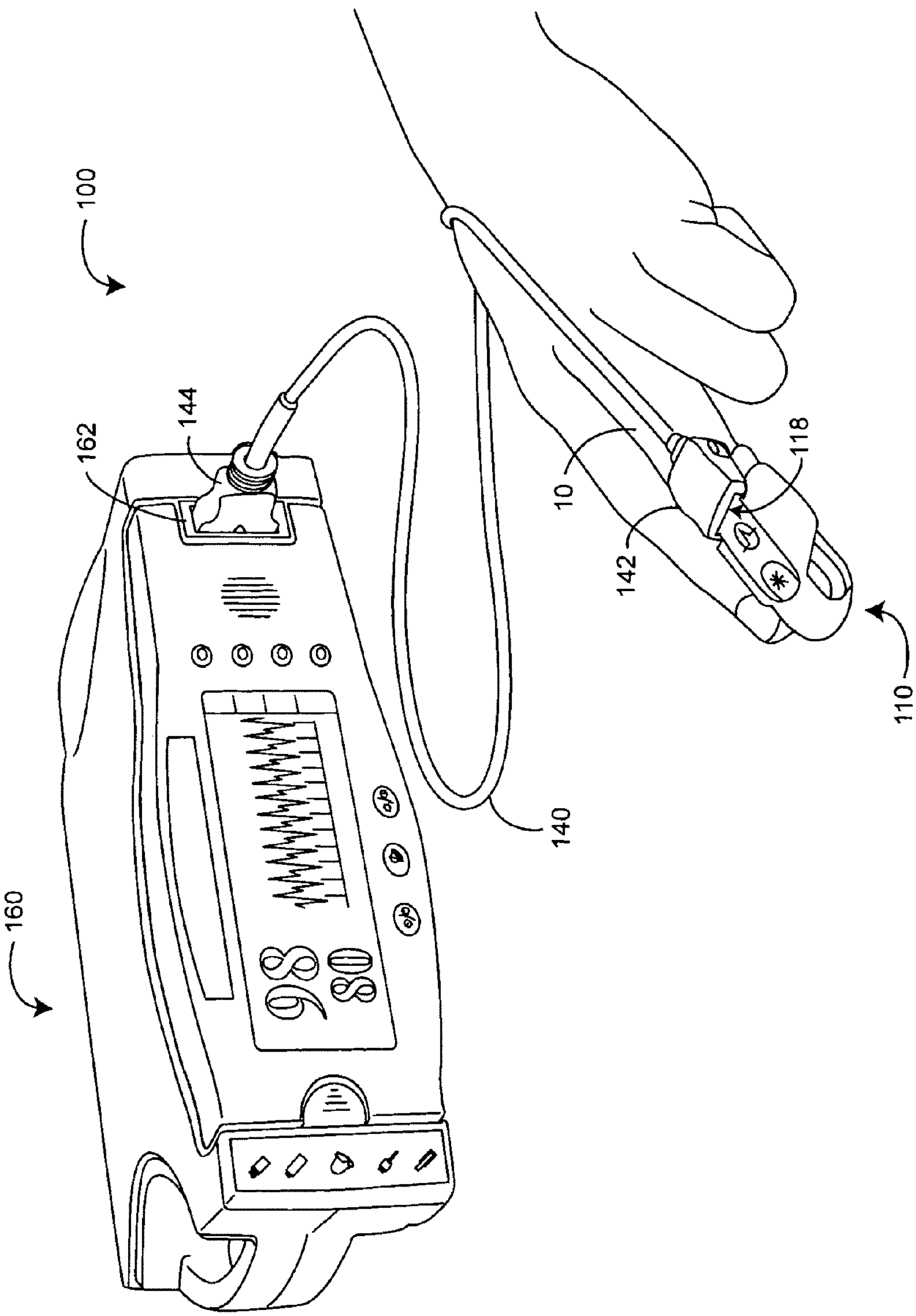


FIG. 1 (Prior Art)

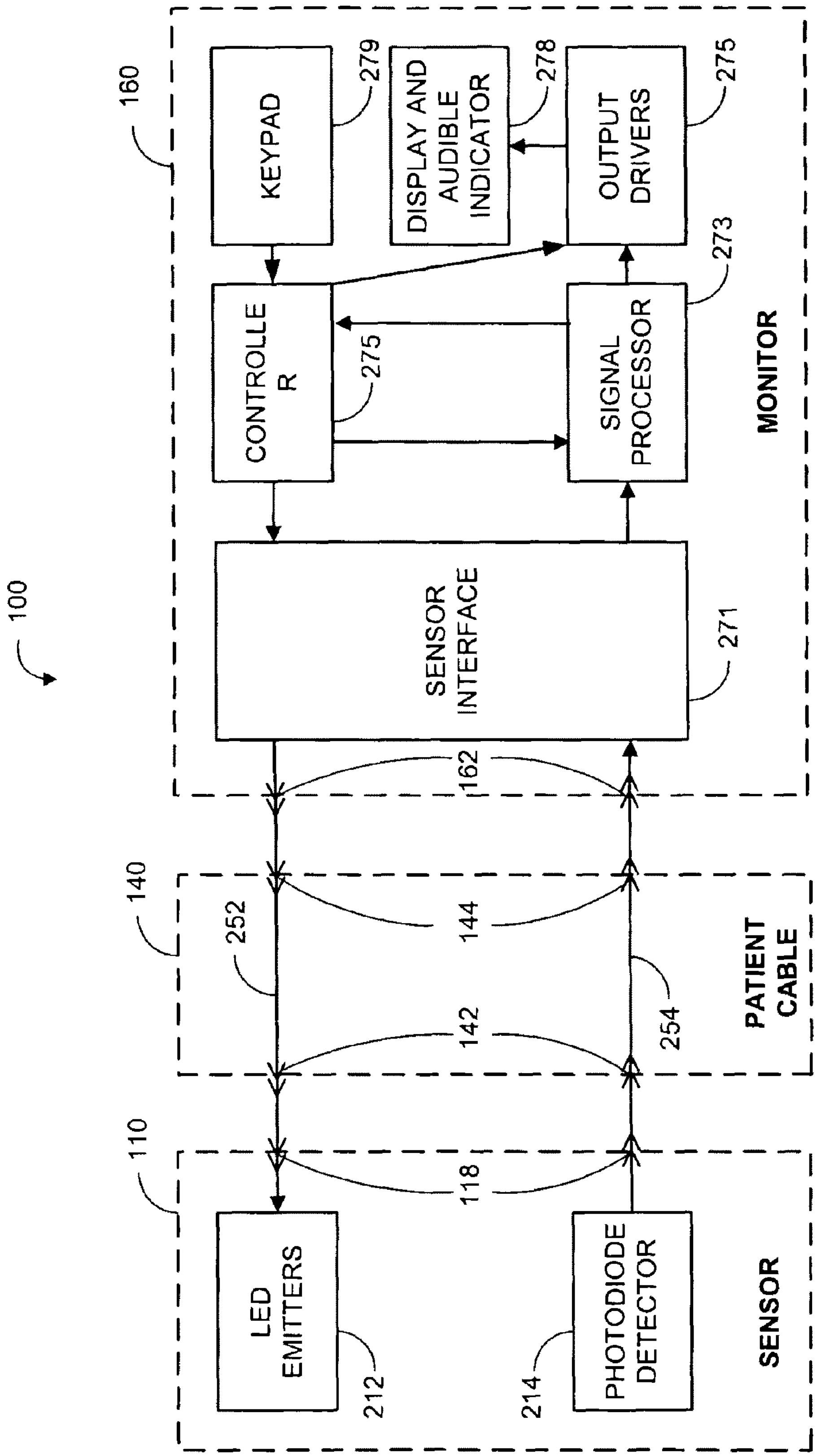


FIG. 2 (Prior Art)

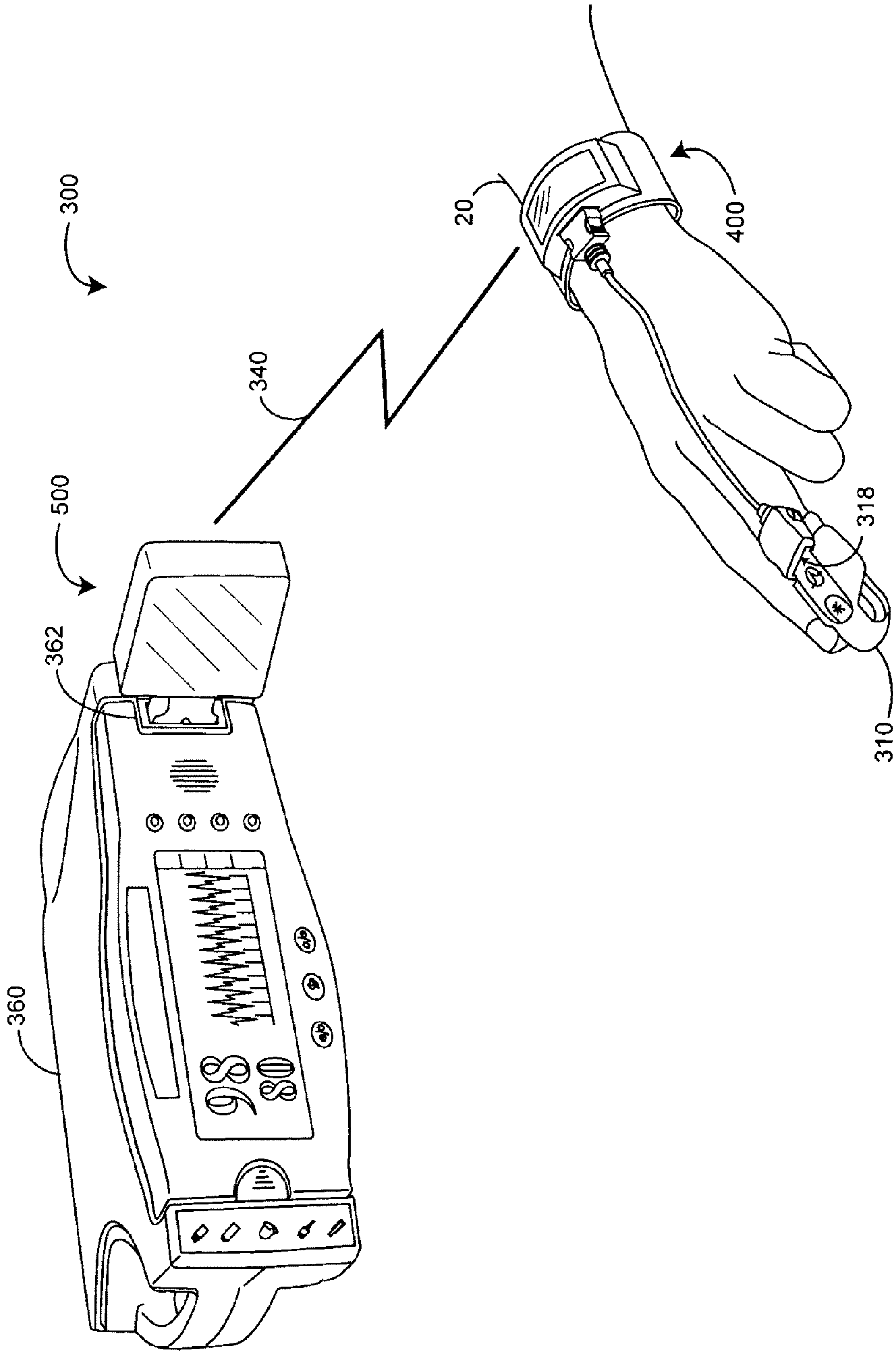
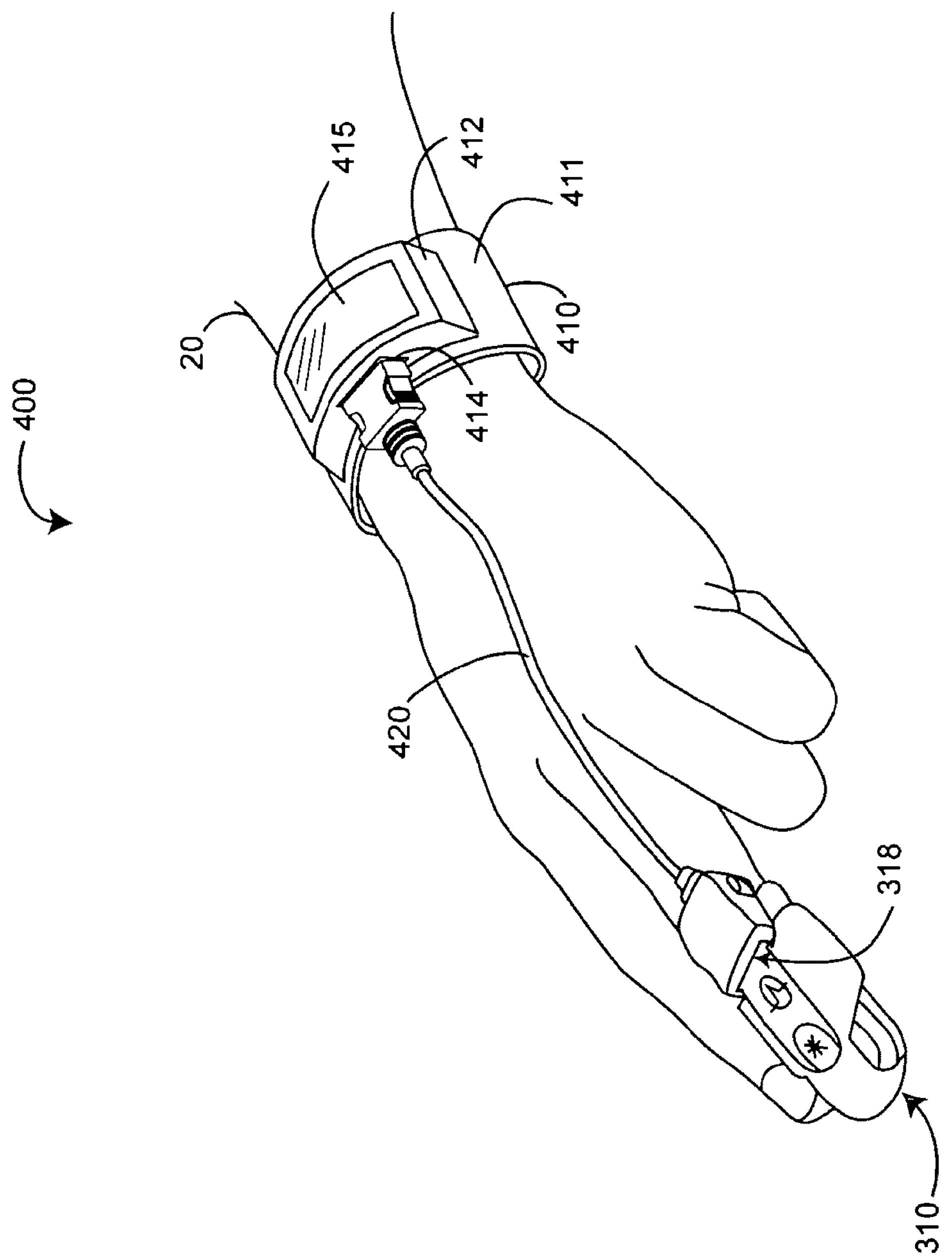


FIG. 3



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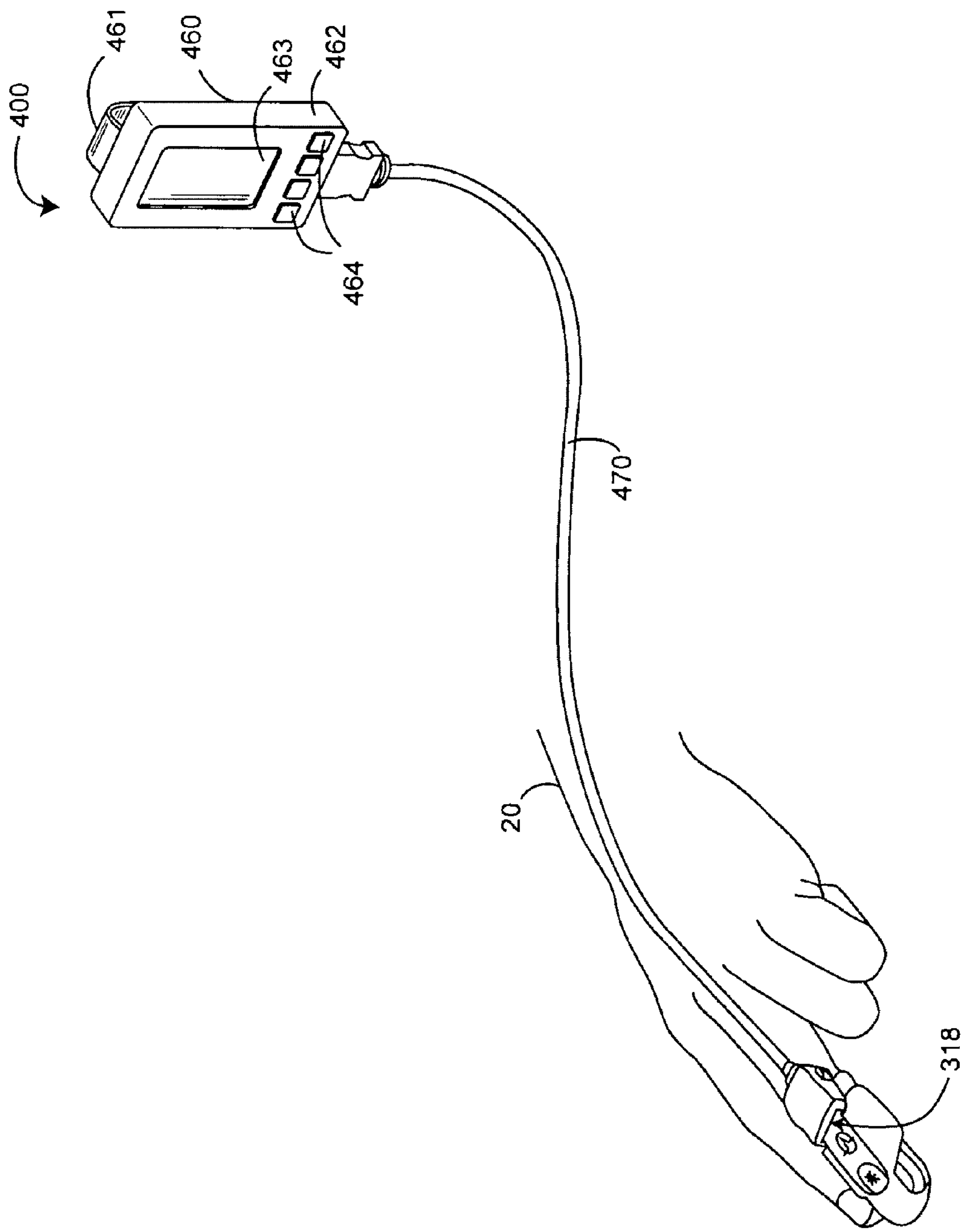


FIG. 4B

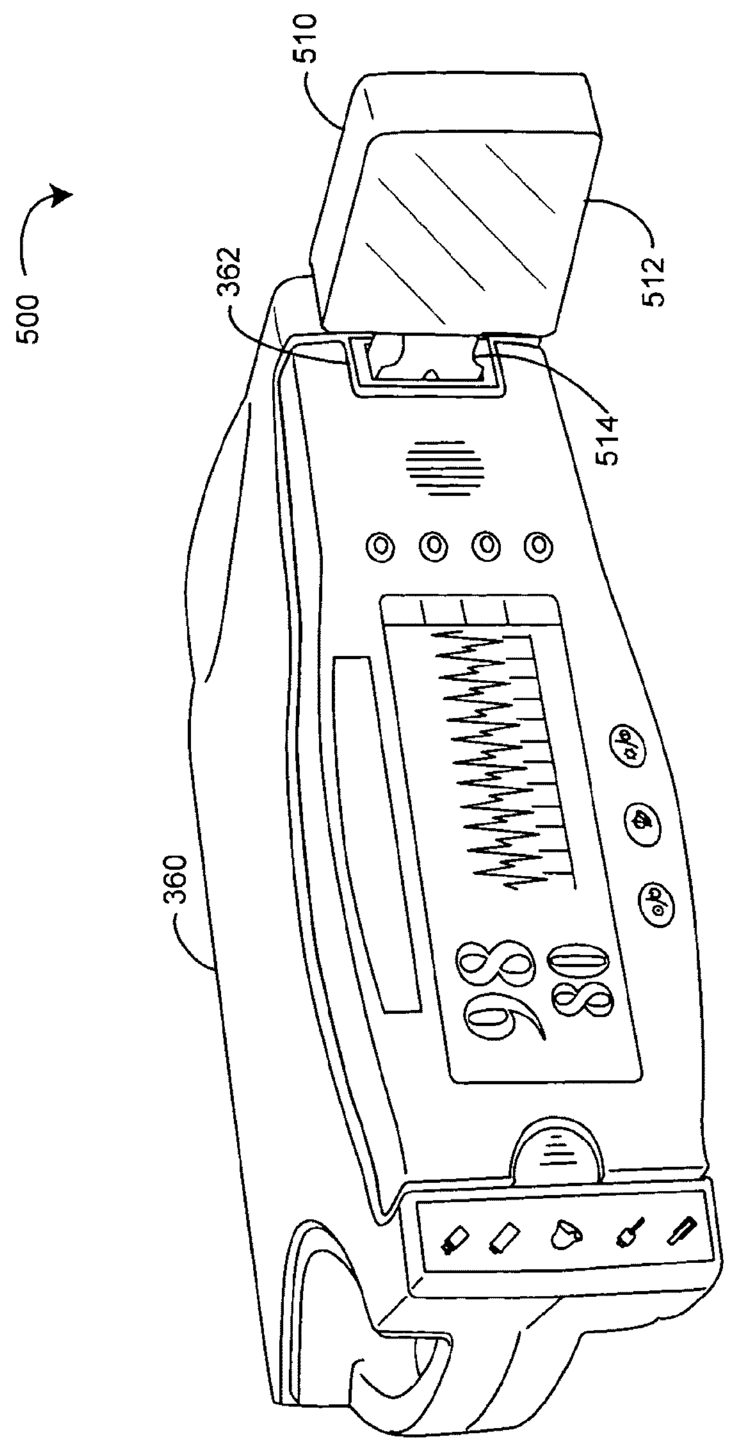


FIG. 5A

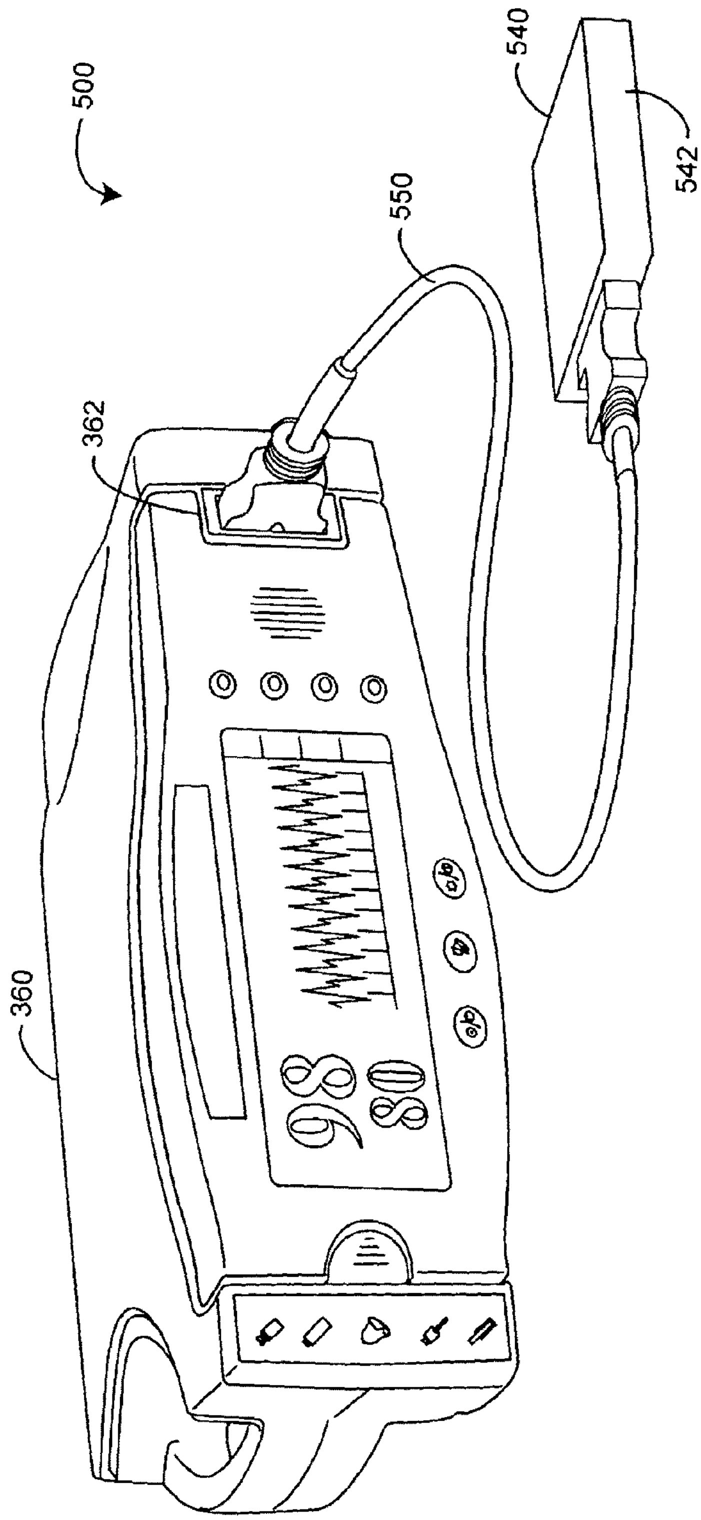


FIG. 5B

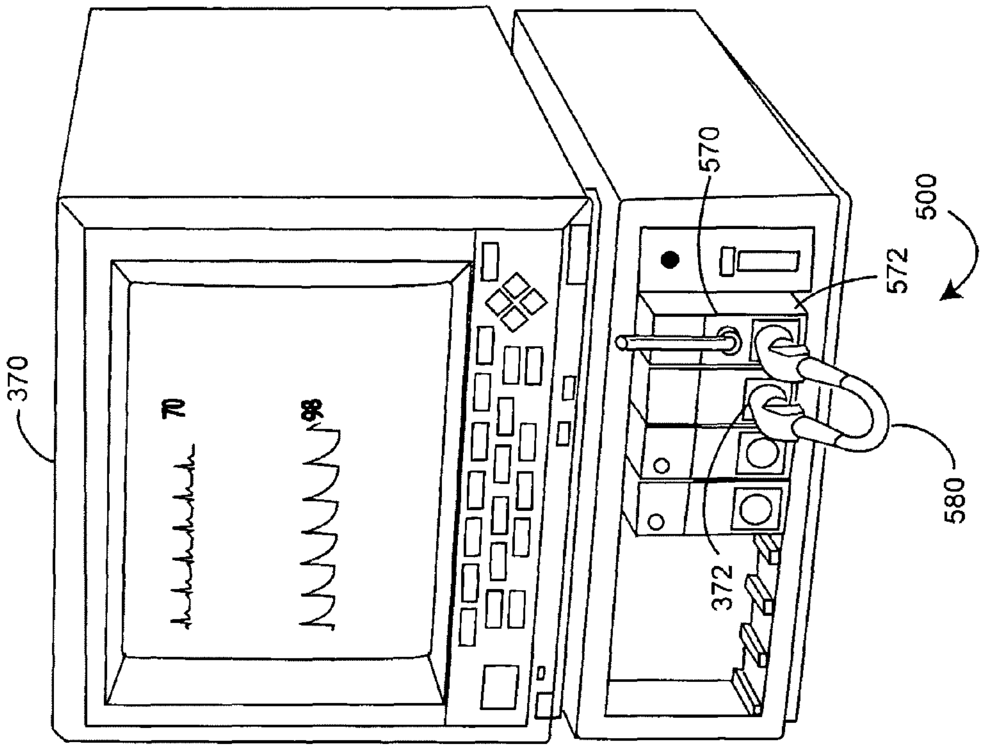
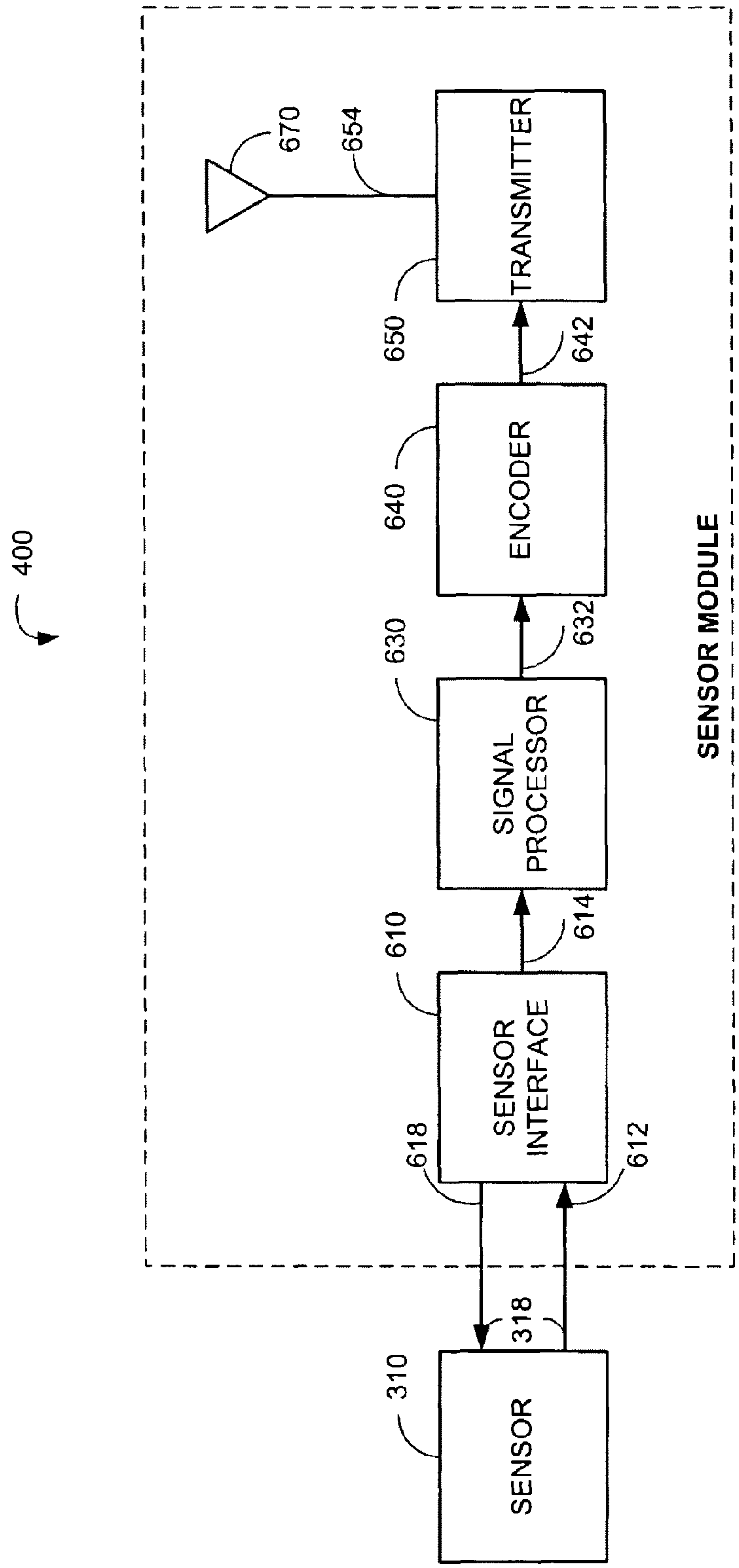


FIG. 5C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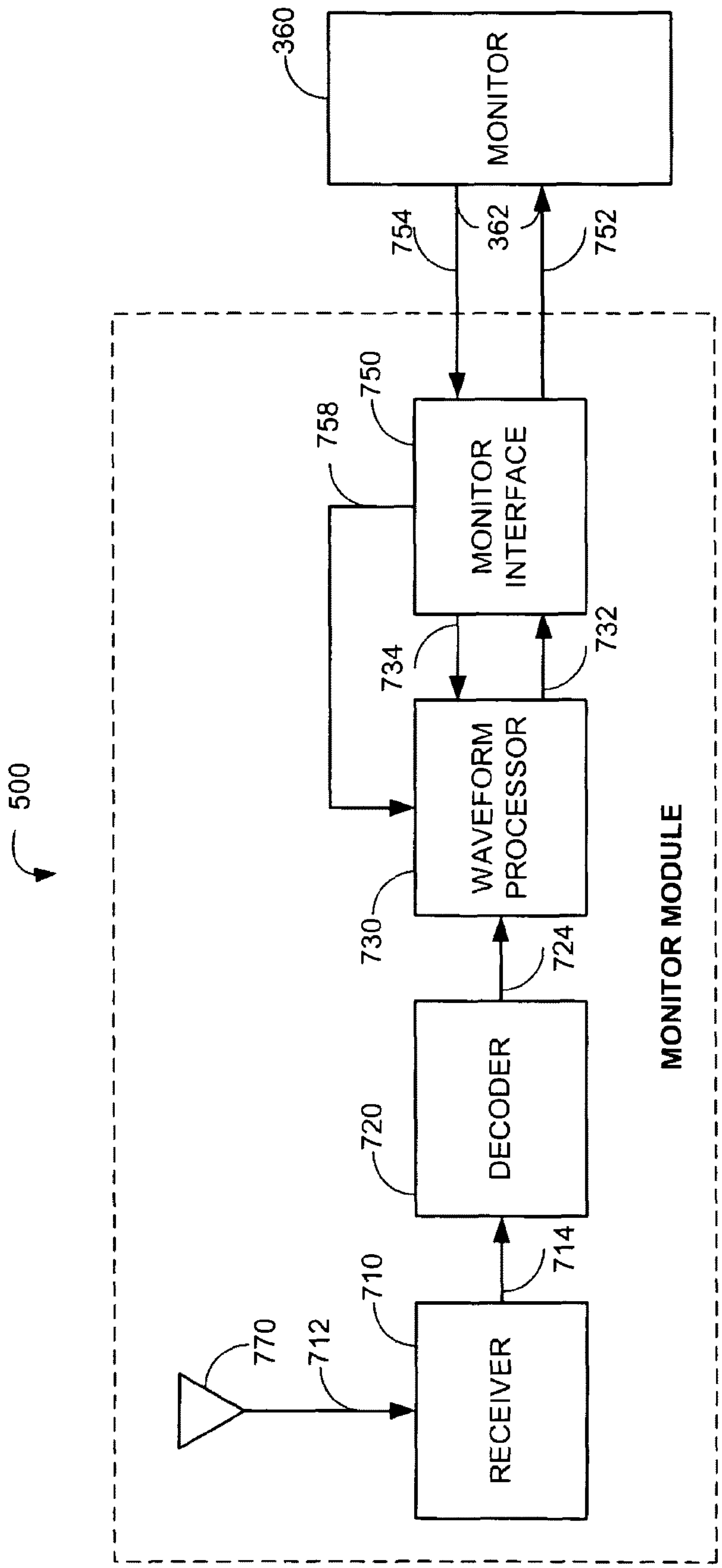
618
612
318
SENSOR
310

FIG. 6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RECEIVER
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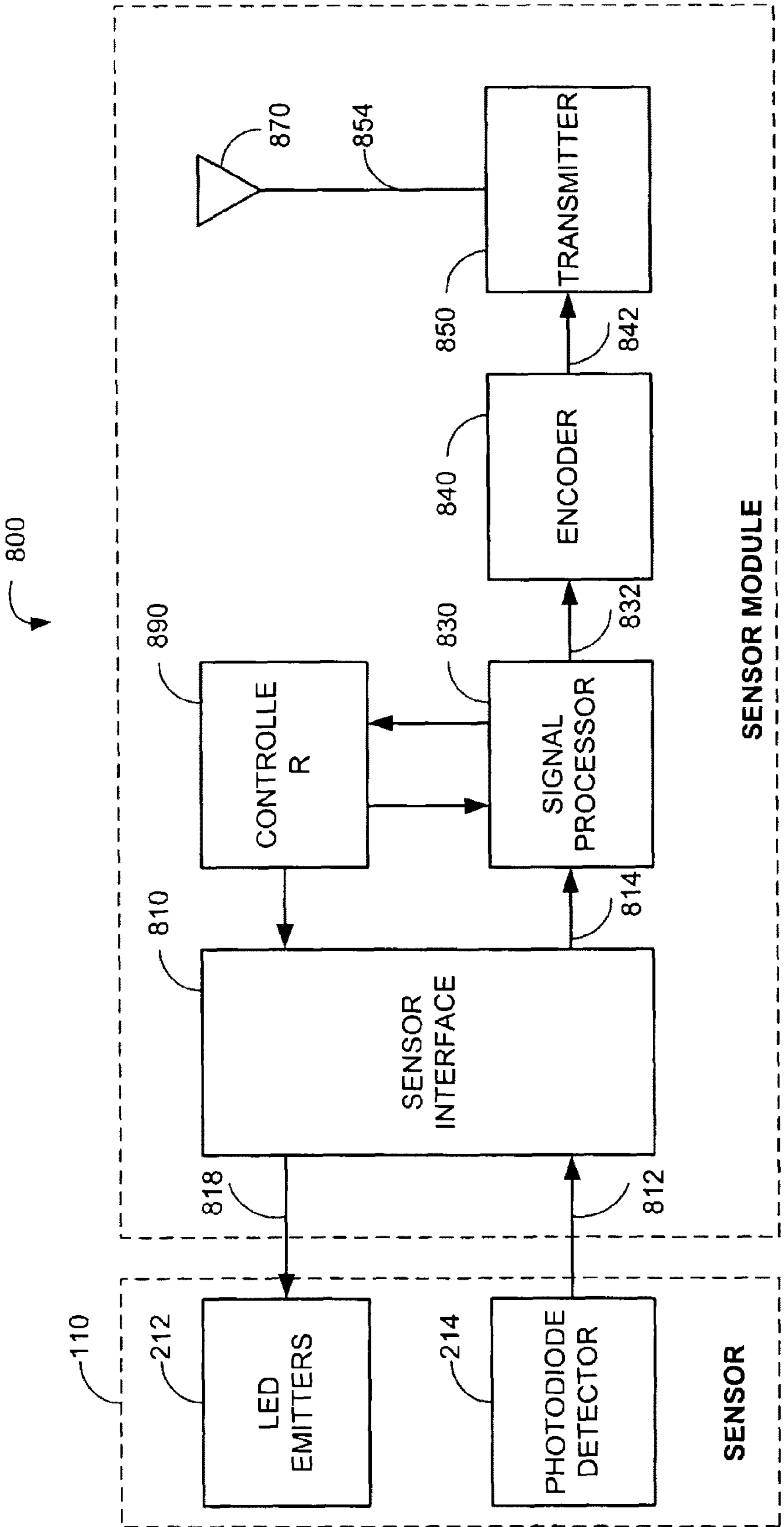
770
MONITOR MODULE

FIG. 7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EMITTERS
214
PHOTODIODE
DETECTOR
SENSOR

FIG. 8

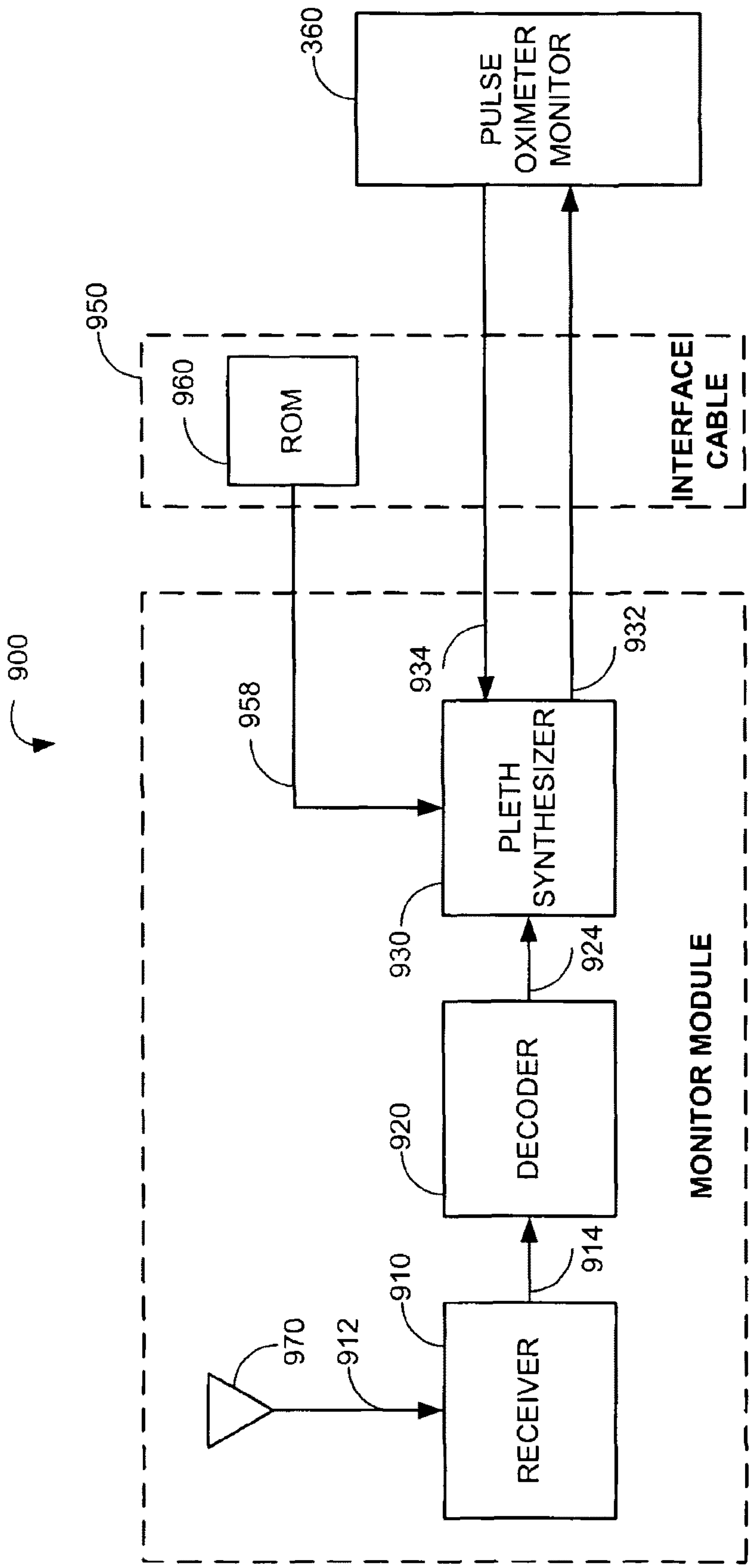
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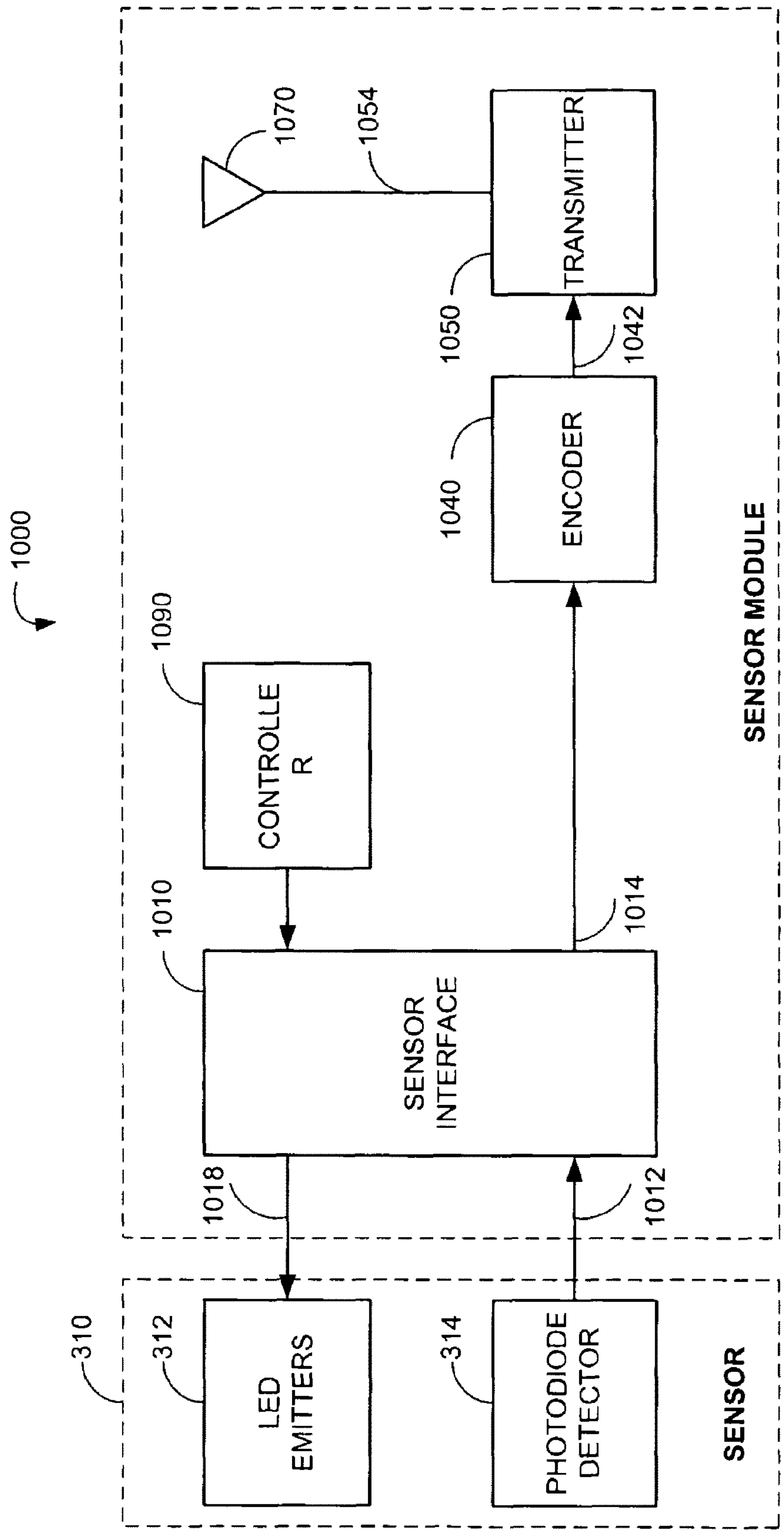
FIG. 9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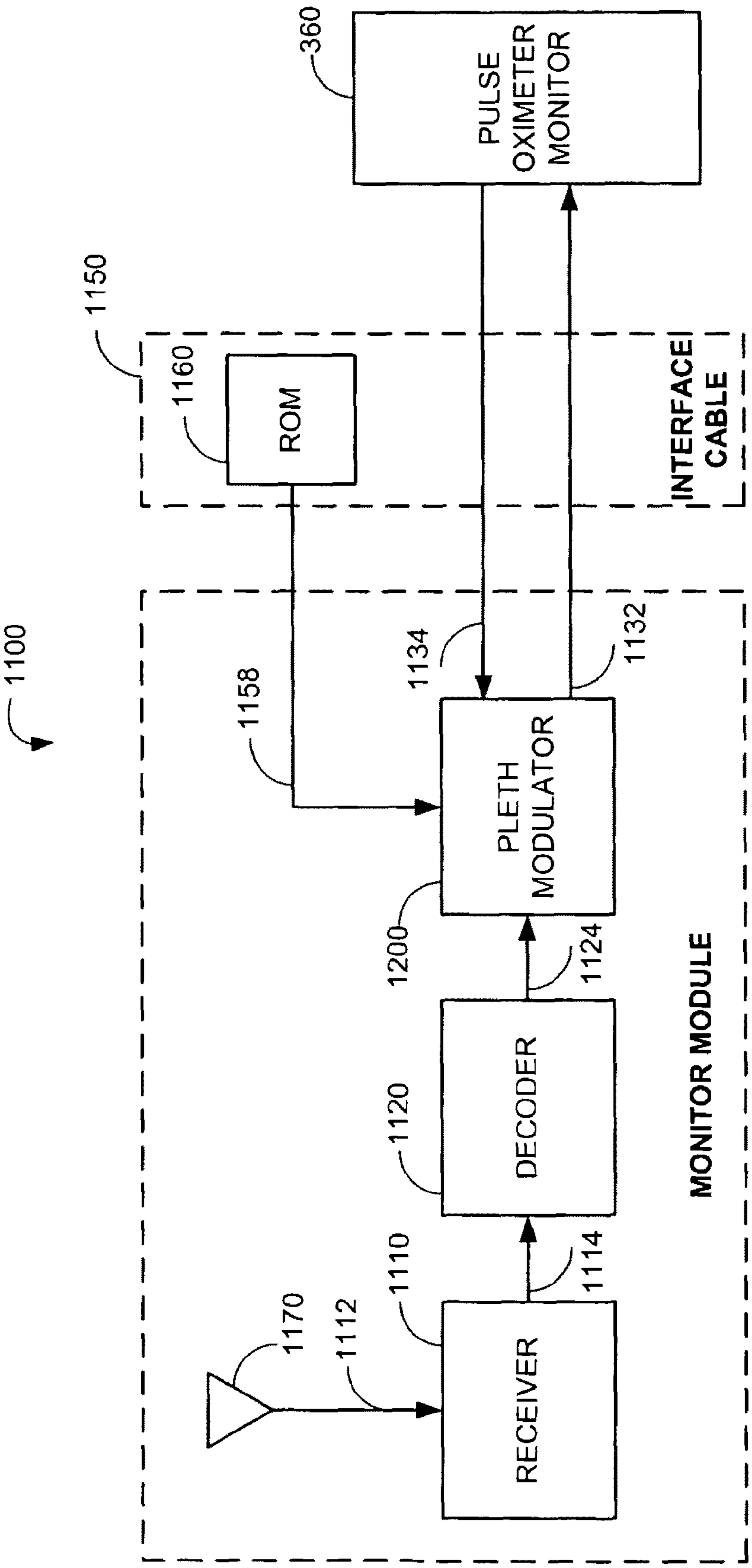
LED
EMITTERS
314
PHOTODIODE
DETECTOR
SENSOR

FIG. 10



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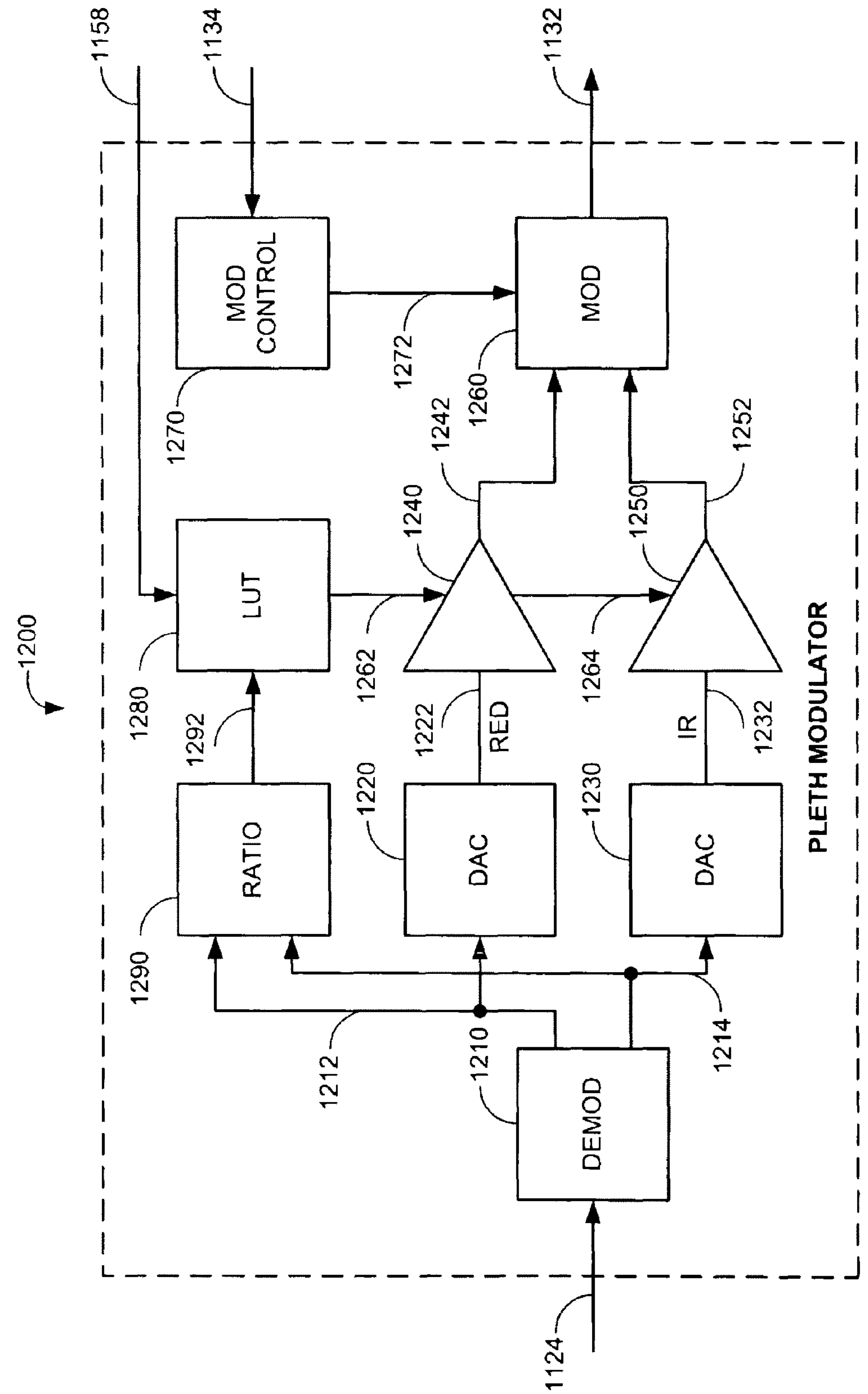
RECEIVER

FIG. 11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1272
1260
LUT
1280
1240
1242
1250
1252
1262
1264
RATIO
1290
1292
DAC
1220
1222
RED
DAC
1230
1232
IR
PLETH MODULATOR
DEMOD
1210
1212
1214
1124

FIG. 12

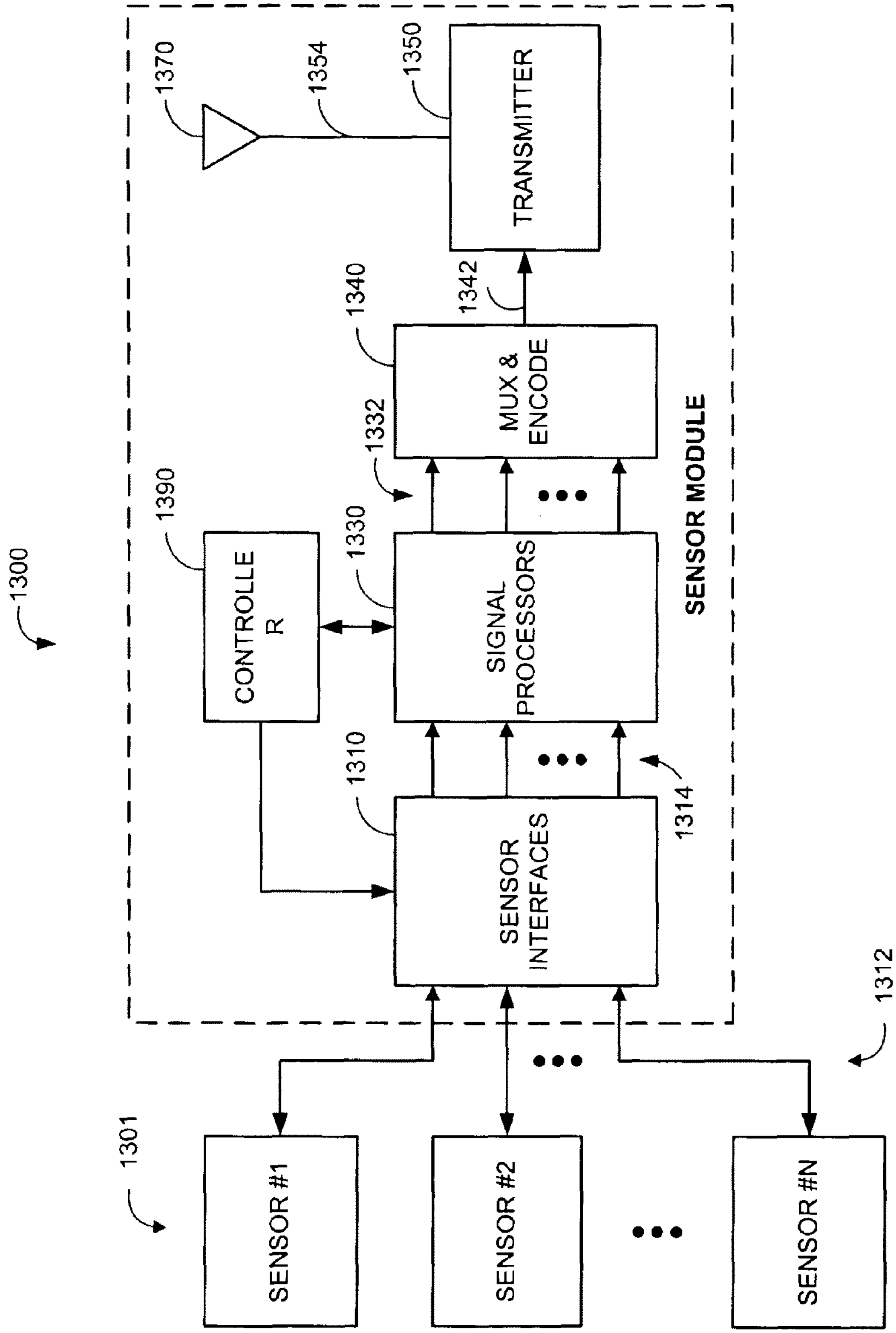
1300
SENSOR MODULE
TRANSMITTER
MUX &
ENCODE
SIGNAL
PROCESSORS
CONTROLLE
R
SENSOR
INTERFACES
SENSOR #1
SENSOR #2
SENSOR #N
1370
1354
1350
1340
1342
1332
1390
1330
1310
1314
1312
1301

FIG. 13

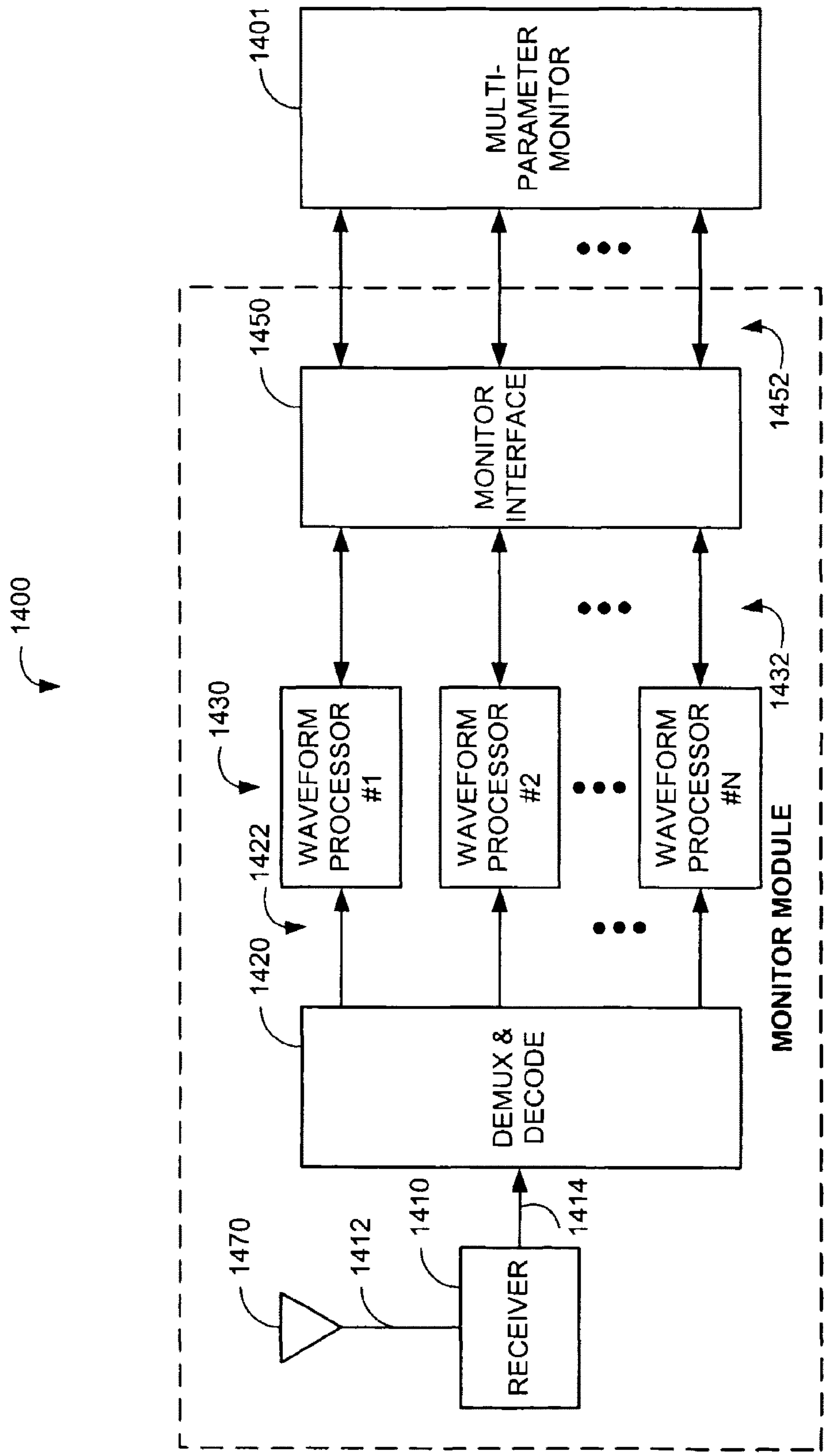
1400
1401
MULTI-
PARAMETER
MONITOR
1450
MONITOR
INTERFACE
1452
1430
WAVEFORM
PROCESSOR
#1
WAVEFORM
PROCESSOR
#2
WAVEFORM
PROCESSOR
#N
1432
1422
1420
DEMUX &
DECODE
MONITOR MODULE
1470
1412
1410
1414
RECEIVER

FIG. 14

WEARABLE PORTABLE PATIENT MONITOR

REFERENCE TO RELATED APPLICATION

The present application is a continuation of U.S. patent application Ser. No. 15/448,989, filed on Mar. 3, 2017, entitled "Physiological Measurement Communications Adapter," which is a continuation of U.S. patent application Ser. No. 14/815,232, filed on Jul. 31, 2015, entitled "Physiological Measurement Communications Adapter," which is a continuation of U.S. patent application Ser. No. 14/217,788, filed on Mar. 18, 2014, entitled "Wrist-Mounted Physiological Measurement Device," now U.S. Pat. No. 9,113,832, which is a continuation of U.S. patent application Ser. No. 14/037,137, filed on Sep. 25, 2013, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 9,113,831, which is a continuation of U.S. patent application Ser. No. 12/955,826, filed on Nov. 29, 2010, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 8,548,548, which is a continuation of U.S. patent application Ser. No. 11/417,006, filed on May 3, 2006, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 7,844,315, which claims priority benefit under 35 U.S.C. §120 to, and is a continuation of, U.S. patent application Ser. No. 11/048,330, filed Feb. 1, 2005, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 7,844,314, which is a continuation of U.S. patent application Ser. No. 10/377,933, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 6,850,788, which claims priority benefit under 35 U.S.C. §119(e) from U.S. Provisional Application No. 60/367,428, filed Mar. 25, 2002, entitled "Physiological Measurement Communications Adapter." The present application also incorporates the foregoing utility disclosures herein by reference.

BACKGROUND OF THE INVENTION

Patient vital sign monitoring may include measurements of blood oxygen, blood pressure, respiratory gas, and EKG among other parameters. Each of these physiological parameters typically requires a sensor in contact with a patient and a cable connecting the sensor to a monitoring device. For example, FIGS. **1-2** illustrate a conventional pulse oximetry system **100** used for the measurement of blood oxygen. As shown in FIG. **1**, a pulse oximetry system has a sensor **110**, a patient cable **140** and a monitor **160**. The sensor **110** is typically attached to a finger **10** as shown. The sensor **110** has a plug **118** that inserts into a patient cable socket **142**. The monitor **160** has a socket **162** that accepts a patient cable plug **144**. The patient cable **140** transmits an LED drive signal **252** (FIG. **2**) from the monitor **160** to the sensor **110** and a resulting detector signal **254** (FIG. **2**) from the sensor **110** to the monitor **160**. The monitor **160** processes the detector signal **254** (FIG. **2**) to provide, typically, a numerical readout of the patient's oxygen saturation, a numerical readout of pulse rate, and an audible indicator or "beep" that occurs in response to each arterial pulse.

As shown in FIG. **2**, the sensor **110** has both red and infrared LED emitters **212** and a photodiode detector **214**. The monitor **160** has a sensor interface **271**, a signal processor **273**, a controller **275**, output drivers **276**, a display and audible indicator **278**, and a keypad **279**. The monitor **160** determines oxygen saturation by computing the differential absorption by arterial blood of the two wavelengths emitted by the sensor emitters **212**, as is well-known in the

art. The sensor interface **271** provides LED drive current **252** which alternately activates the red and IR LED emitters **212**. The photodiode detector **214** generates a signal **254** corresponding to the red and infrared light energy attenuated from transmission through the patient finger **10** (FIG. **1**). The sensor interface **271** also has input circuitry for amplification, filtering and digitization of the detector signal **254**. The signal processor **273** calculates a ratio of detected red and infrared intensities, and an arterial oxygen saturation value is empirically determined based on that ratio. The controller **275** provides hardware and software interfaces for managing the display and audible indicator **278** and keypad **279**. The display and audible indicator **278** shows the computed oxygen status, as described above, and provides the pulse beep as well as alarms indicating oxygen desaturation events. The keypad **279** provides a user interface for setting alarm thresholds, alarm enablement, and display options, to name a few.

SUMMARY OF THE INVENTION

Conventional physiological measurement systems are limited by the patient cable connection between sensor and monitor. A patient must be located in the immediate vicinity of the monitor. Also, patient relocation requires either disconnection of monitoring equipment and a corresponding loss of measurements or an awkward simultaneous movement of patient equipment and cables. Various devices have been proposed or implemented to provide wireless communication links between sensors and monitors, freeing patients from the patient cable tether. These devices, however, are incapable of working with the large installed base of existing monitors and sensors, requiring caregivers and medical institutions to suffer expensive wireless upgrades. It is desirable, therefore, to provide a communications adapter that is plug-compatible both with existing sensors and monitors and that implements a wireless link replacement for the patient cable.

An aspect of a physiological measurement communications adapter comprises a sensor interface configured to receive a sensor signal. A transmitter modulates a first baseband signal responsive to the sensor signal so as to generate a transmit signal. A receiver demodulates a receive signal corresponding to the transmit signal so as to generate a second baseband signal corresponding to the first baseband signal. Further, a monitor interface is configured to communicate a waveform responsive to the second baseband signal to a sensor port of a monitor. The waveform is adapted to the monitor so that measurements derived by the monitor from the waveform are generally equivalent to measurements derivable from the sensor signal. The communications adapter may further comprise a signal processor having an input in communications with the sensor interface, where the signal processor is operable to derive a parameter responsive to the sensor signal and where the first baseband signal is responsive to the parameter. The parameter may correspond to at least one of a measured oxygen saturation and a pulse rate.

One embodiment may further comprise a waveform generator that synthesizes the waveform from a predetermined shape. The waveform generator synthesizes the waveform at a frequency adjusted to be generally equivalent to the pulse rate. The waveform may have a first amplitude and a second amplitude, and the waveform generator may be configured to adjusted the amplitudes so that measurements derived by the monitor are generally equivalent to a measured oxygen saturation.

In another embodiment, the sensor interface is operable on the sensor signal to provide a plethysmograph signal output, where the first baseband signal is responsive to the plethysmograph signal. This embodiment may further comprise a waveform modulator that modifies a decoded signal responsive to the second baseband signal to provide the waveform. The waveform modulator may comprise a demodulator that separates a first signal and a second signal from the decoded signal, an amplifier that adjusts amplitudes of the first and second signals to generate a first adjusted signal and a second adjusted signal, and a modulator that combines the first and second adjusted signals into the waveform. The amplitudes of the first and second signals may be responsive to predetermined calibration data for the sensor and the monitor.

An aspect of a physiological measurement communications adapter method comprises the steps of inputting a sensor signal at a patient location, communicating patient data derived from the sensor signal between the patient location and a monitor location, constructing a waveform at the monitor location responsive to the sensor signal, and providing the waveform to a monitor via a sensor port. The waveform is constructed so that the monitor calculates a parameter generally equivalent to a measurement derivable from the sensor signal.

In one embodiment, the communicating step may comprise the substeps of deriving a conditioned signal from the sensor signal, calculating a parameter signal from the conditioned signal, and transmitting the parameter signal from the patient location to the monitor location. The constructing step may comprise the substep of synthesizing the waveform from the parameter signal. In an alternative embodiment, the communicating step may comprise the substeps of deriving a conditioned signal from said sensor signal and transmitting the conditioned signal from the patient location to the monitor location. The constructing step may comprise the substeps of demodulating the conditioned signal and remodulating the conditioned signal to generate the waveform. The providing step may comprise the substeps of inputting a monitor signal from an LED drive output of the sensor port, modulating the waveform in response to the monitor signal, and outputting the waveform on a detector input of the sensor port.

Another aspect of a physiological measurement communications adapter comprises a sensor interface means for inputting a sensor signal and outputting a conditioned signal, a transmitter means for sending data responsive to the sensor signal, and a receiver means for receiving the data. The communications adapter further comprises a waveform processor means for constructing a waveform from the data so that measurements derived by a monitor from the waveform are generally equivalent to measurements derivable from the sensor signal, and a monitor interface means for communicating the waveform to a sensor port of the monitor. The communications adapter may further comprise a signal processor means for deriving a parameter signal from the conditioned signal, where the data comprises the parameter signal. The waveform processor means may comprise a means for synthesizing the waveform from the parameter signal. The data may comprise the conditioned signal, and the waveform processor means may comprise a means for modulating the conditioned signal in response to the monitor.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an illustration of a prior art pulse oximetry system;

FIG. **2** is a functional block diagram of a prior art pulse oximetry system;

FIG. **3** is an illustration of a physiological measurement communications adapter;

FIGS. **4**A-B are illustrations of communications adapter sensor modules;

FIGS. **5**A-C are illustrations of communications adapter monitor modules;

FIG. **6** is a functional block diagram of a communications adapter sensor module;

FIG. **7** is a functional block diagram of a communications adapter monitor module;

FIG. **8** is a functional block diagram of a sensor module configured to transmit measured pulse oximeter parameters;

FIG. **9** is a functional block diagram of a monitor module configured to received measured pulse oximeter parameters;

FIG. **10** is a functional block diagram of a sensor module configured to transmit a plethysmograph;

FIG. **11** is a functional block diagram of a monitor module configured to receive a plethysmograph;

FIG. **12** is a functional block diagram of a waveform modulator;

FIG. **13** is a functional block diagram of a sensor module configured for multiple sensors; and

FIG. **14** is a functional block diagram of a monitor module configured for multiple sensors.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Overview

FIG. **3** illustrates one embodiment of a communications adapter. FIGS. **4-5** illustrate physical configurations for a communications adapter. In particular, FIGS. **4**A-B illustrate sensor module configurations and FIGS. **5**A-C illustrate monitor module configurations. FIGS. **6-14** illustrate communications adapter functions. In particular, FIGS. **6-7** illustrate general functions for a sensor module and a monitor module, respectively. FIGS. **8-9** functionally illustrate a communications adapter where derived pulse oximetry parameters, such as saturation and pulse rate are transmitted between a sensor module and a monitor module. Also, FIGS. **10-12** functionally illustrate a communications adapter where a plethysmograph is transmitted between a sensor module and a monitor module. FIGS. **13-14** functionally illustrate a multiple-parameter communications adapter.

FIG. **3** illustrates a communications adapter **300** having a sensor module **400** and a monitor module **500**. The communications adapter **300** communicates patient data derived from a sensor **310** between the sensor module **400**, which is located proximate a patient **20** and the monitor module **500**, which is located proximate a monitor **360**. A wireless link **340** is provided between the sensor module **400** and the monitor module **500**, replacing the conventional patient cable, such as a pulse oximetry patient cable **140** (FIG. **1**). Advantageously, the sensor module **400** is plug-compatible with a conventional sensor **310**. In particular, the sensor connector **318** connects to the sensor module **400** in a similar manner as to a patient cable. Further, the sensor module **400** outputs a drive signal to the sensor **310** and inputs a sensor signal from the sensor **310** in an equivalent manner as a conventional monitor **360**. The sensor module **400** may be battery powered or externally powered. External power may be for recharging internal batteries or for powering the sensor module during operation or both.

As shown in FIG. **3**, the monitor module **500** is advantageously plug-compatible with a conventional monitor **360**. In particular, the monitor's sensor port **362** connects to the monitor module **500** in a similar manner as to a patient cable, such as a pulse oximetry patient cable **140** (FIG. **1**). Further, the monitor module **500** inputs a drive signal from the monitor **360** and outputs a corresponding sensor signal to the monitor **360** in an equivalent manner as a conventional sensor **310**. As such, the combination sensor module **400** and monitor module **500** provide a plug-compatible wireless replacement for a patient cable, adapting an existing wired physiological measurement system into a wireless physiological measurement system. The monitor module **500** may be battery powered, powered from the monitor, such as by tapping current from a monitor's LED drive, or externally powered from an independent AC or DC power source.

Although a communications adapter **300** is described herein with respect to a pulse oximetry sensor and monitor, one of ordinary skill in the art will recognize that a communications adapter may provide a plug-compatible wireless replace for a patient cable that connects any physiological sensor and corresponding monitor. For example, a communications adapter **300** may be applied to a biopotential sensor, a non-invasive blood pressure (NIBP) sensor, a respiratory rate sensor, a glucose sensor and the corresponding monitors, to name a few.

Sensor Module Physical Configurations

FIGS. **4**A-B illustrate physical embodiments of a sensor module **400**. FIG. **4**A illustrates a wrist-mounted module **410** having a wrist strap **411**, a case **412** and an auxiliary cable **420**. The case **412** contains the sensor module electronics, which are functionally described with respect to FIG. **6**, below. The case **412** is mounted to the wrist strap **411**, which attaches the wrist-mounted module **410** to a patient **20**. The auxiliary cable **420** mates to a sensor connector **318** and a module connector **414**, providing a wired link between a conventional sensor **310** and the wrist-mounted module **410**. Alternatively, the auxiliary cable **420** is directly wired to the sensor module **400**. The wrist-mounted module **410** may have a display **415** that shows sensor measurements, module status and other visual indicators, such as monitor status. The wrist-mounted module **410** may also have keys (not shown) or other input mechanisms to control its operational mode and characteristics. In an alternative embodiment, the sensor **310** may have a tail (not shown) that connects directly to the wrist-mounted module **410**, eliminating the auxiliary cable **420**.

FIG. **4**B illustrates a clip-on module **460** having a clip **461**, a case **462** and an auxiliary cable **470**. The clip **461** attaches the clip-on module **460** to patient clothing or objects near a patient **20**, such as a bed frame. The auxiliary cable **470** mates to the sensor connector **318** and functions as for the auxiliary cable **420** (FIG. **4**A) of the wrist-mounted module **410** (FIG. **4**A), described above. The clip-on module **460** may have a display **463** and keys **464** as for the wrist-mounted module **410** (FIG. **4**A). Either the wrist-mounted module **410** or the clip-on module **460** may have other input or output ports (not shown) that download software, configure the module, or provide a wired connection to other measurement instruments or computing devices, to name a few examples.

Monitor Module Physical Configurations

FIGS. **5**A-C illustrate physical embodiments of a monitor module **500**. FIG. **5**A illustrates a direct-connect module **510** having a case **512** and an integrated monitor connector **514**. The case **512** contains the monitor module electronics, which are functionally described with respect to FIG. **7**, below. The monitor connector **514** mimics that of the monitor end of a patient cable, such as a pulse oximetry patient cable **140** (FIG. **1**), and electrically and mechanically connects the monitor module **510** to the monitor **360** via the monitor's sensor port **362**.

FIG. **5**B illustrates a cable-connect module **540** having a case **542** and an auxiliary cable **550**. The case **542** functions as for the direct-connect module **510** (FIG. **5**A), described above. Instead of directly plugging into the monitor **360**, the cable-connect module **540** utilizes the auxiliary cable **550**, which mimics the monitor end of a patient cable, such as a pulse oximetry patient cable **140** (FIG. **1**), and electrically connects the cable-connect module **540** to the monitor sensor port **362**.

FIG. **5**C illustrates a plug-in module **570** having a plug-in case **572** and an auxiliary cable **580**. The plug-in case **572** is mechanically compatible with the plug-in chassis of a multiparameter monitor **370** and may or may not electrically connect to the chassis backplane. The auxiliary cable **580** mimics a patient cable and electrically connects the plug-in module **570** to the sensor port **372** of another plug-in device. A direct-connect module **510** (FIG. **5**A) or a cable-connect module **540** (FIG. **5**B) may also be used with a multiparameter monitor **370**.

In a multiparameter embodiment, such as described with respect to FIGS. **13-14**, below, a monitor module **500** may connect to multiple plug-in devices of a multiparameter monitor **370**. For example, a cable-connect module **540** (FIG. **5**B) may have multiple auxiliary cables **550** (FIG. **5**B) that connect to multiple plug-in devices installed within a multiparameter monitor chassis. Similarly, a plug-in module **570** may have one or more auxiliary cables **580** with multiple connectors for attaching to the sensor ports **372** of multiple plug-in devices.

Communications Adapter Functions

FIGS. **6-7** illustrate functional embodiments of a communications adapter. FIG. **6** illustrates a sensor module **400** having a sensor interface **610**, a signal processor **630**, an encoder **640**, a transmitter **650** and a transmitting antenna **670**. A physiological sensor **310** provides an input sensor signal **612** at the sensor connector **318**. Depending on the sensor **310**, the sensor module **400** may provide one or more drive signals **618** to the sensor **310**. The sensor interface **610** inputs the sensor signal **612** and outputs a conditioned signal **614**. The conditioned signal **614** may be coupled to the transmitter **650** or further processed by a signal processor **630**. If the sensor module configuration utilizes a signal processor **630**, it derives a parameter signal **632** responsive to the sensor signal **612**, which is then coupled to the transmitter **650**. Regardless, the transmitter **650** inputs a baseband signal **642** that is responsive to the sensor signal **612**. The transmitter **650** modulates the baseband signal **642** with a carrier to generate a transmit signal **654**. The transmit signal **654** may be derived by various amplitude, frequency or phase modulation schemes, as is well known in the art. The transmit signal **654** is coupled to the transmit antenna **670**, which provides wireless communications to a corresponding receive antenna **770** (FIG. **7**), as described below.

As shown in FIG. **6**, the sensor interface **610** conditions and digitizes the sensor signal **612** to generate the conditioned signal **614**. Sensor signal conditioning may be performed in the analog domain or digital domain or both and may include amplification and filtering in the analog domain and filtering, buffering and data rate modification in the digital domain, to name a few. The resulting conditioned signal **614** is responsive to the sensor signal **612** and may be used to calculate or derive a parameter signal **632**.

Further shown in FIG. **6**, the signal processor **630** performs signal processing on the conditioned signal **614** to generate the parameter signal **632**. The signal processing may include buffering, digital filtering, smoothing, averaging, adaptive filtering and frequency transforms to name a few. The resulting parameter signal **632** may be a measurement calculated or derived from the conditioned signal, such as oxygen saturation, pulse rate, blood glucose, blood pressure and EKG to name a few. Also, the parameter signal **632** may be an intermediate result from which the above-stated measurements may be calculated or derived.

As described above, the sensor interface **610** performs mixed analog and digital pre-processing of an analog sensor signal and provides a digital output signal to the signal processor **630**. The signal processor **630** then performs digital post-processing of the front-end processor output. In alternative embodiments, the input sensor signal **612** and the output conditioned signal **614** may be either analog or digital, the front-end processing may be purely analog or purely digital, and the back-end processing may be purely analog or mixed analog or digital.

In addition, FIG. **6** shows an encoder **640**, which translates a digital word or serial bit stream, for example, into the baseband signal **642**, as is well-known in the art. The baseband signal **642** comprises the symbol stream that drives the transmit signal **654** modulation, and may be a single signal or multiple related signal components, such as in-phase and quadrature signals. The encoder **640** may include data compression and redundancy, also well-known in the art.

FIG. **7** illustrates a monitor module **500** having a receive antenna **770**, a receiver **710**, a decoder **720**, a waveform processor **730** and a monitor interface **750**. A receive signal **712** is coupled from the receive antenna **770**, which provides wireless communications to a corresponding transmit antenna **670** (FIG. **6**), as described above. The receiver **710** inputs the receive signal **712**, which corresponds to the transmit signal **654** (FIG. **6**). The receiver **710** demodulates the receive signal to generate a baseband signal **714**. The decoder **720** translates the symbols of the demodulated baseband signal **714** into a decoded signal **724**, such as a digital word stream or bit stream. The waveform processor **730** inputs the decoded signal **724** and generates a constructed signal **732**. The monitor interface **750** is configured to communicate the constructed signal **732** to a sensor port **362** of a monitor **360**. The monitor **360** may output a sensor drive signal **754**, which the monitor interface **750** inputs to the waveform processor **730** as a monitor drive signal **734**. The waveform processor **730** may utilize the monitor drive signal **734** to generate the constructed signal **732**. The monitor interface **750** may also provide characterization information **758** to the waveform processor **730**, relating to the monitor **360**, the sensor **310** or both, that the waveform processor **730** utilizes to generate the constructed signal **732**.

The constructed signal **732** is adapted to the monitor **360** so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent to measurements derivable from the sensor signal **612** (FIG. **6**). Note that the sensor **310** (FIG. **6**) may or may not be directly compatible with the monitor **360**. If the sensor **310** (FIG. **6**) is compatible with the monitor **360**, the constructed signal **732** is generated so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent (within clinical significance) with those derivable directly from the sensor signal **612** (FIG. **6**). If the sensor **310** (FIG. **6**) is not compatible with the monitor **360**, the constructed signal **732** is generated so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent to those derivable directly from the sensor signal **612** (FIG. **6**) using a compatible monitor.

Wireless Pulse Oximetry

FIGS. **8-11** illustrate pulse oximeter embodiments of a communications adapter. FIGS. **8-9** illustrate a sensor module and a monitor module, respectively, configured to communicate measured pulse oximeter parameters. FIG. **10-11** illustrate a sensor module and a monitor module, respectively, configured to communicate a plethysmograph signal.

Parameter Transmission

FIG. **8** illustrates a pulse oximetry sensor module **800** having a sensor interface **810**, signal processor **830**, encoder **840**, transmitter **850**, transmitting antenna **870** and controller **890**. The sensor interface **810**, signal processor **830** and controller **890** function as described with respect to FIG. **2**, above. The sensor interface **810** communicates with a standard pulse oximetry sensor **310**, providing an LED drive signal **818** to the LED emitters **312** and receiving a sensor signal **812** from the detector **314** in response. The sensor interface **810** provides front-end processing of the sensor signal **812**, also described above, providing a plethysmograph signal **814** to the signal processor **830**. The signal processor **830** then derives a parameter signal **832** that comprises a real time measurement of oxygen saturation and pulse rate. The parameter signal **832** may include other parameters, such as measurements of perfusion index and signal quality. In one embodiment, the signal processor is an MS-5 or MS-7 board available from Masimo Corporation, Irvine, Calif.

As shown in FIG. **8**, the encoder **840**, the transmitter **850** and the transmitting antenna **870** function as described with respect to FIG. **6**, above. For example, the parameter signal **832** may be a digital word stream that is serialized into a bit stream and encoded into a baseband signal **842**. The baseband signal **842** may be, for example, two bit symbols that drive a quadrature phase shift keyed (QPSK) modulator in the transmitter **850**. Other encodings and modulations are also applicable, as described above. The transmitter **850** inputs the baseband signal **842** and generates a transmit signal **854** that is a modulated carrier having a frequency suitable for short-range transmission, such as within a hospital room, doctor's office, emergency vehicle or critical care ward, to name a few. The transmit signal **854** is coupled to the transmit antenna **870**, which provides wireless communications to a corresponding receive antenna **970** (FIG. **9**), as described below.

FIG. **9** illustrates a monitor module **900** having a receive antenna **970**, a receiver **910**, a decoder **920**, a waveform generator **930** and an interface cable **950**. The receive antenna **970**, receiver **910** and decoder **920** function as described with respect to FIG. **7**, above. In particular, the receive signal **912** is coupled from the receive antenna **970**, which provides wireless communications to a corresponding transmit antenna **870** (FIG. **8**). The receiver **910** inputs the receive signal **912**, which corresponds to the transmit signal **854** (FIG. **8**). The receiver **810** demodulates the receive signal **912** to generate a baseband signal **914**. Not accounting for transmission errors, the baseband signal **914** corresponds to the sensor module baseband signal **842** (FIG. **8**), for example a symbol stream of two bits each. The decoder **920** assembles the baseband signal **914** into a parameter signal **924**, which, for example, may be a sequence of digital words corresponding to oxygen saturation and pulse rate. Again, not accounting for transmission errors, the monitor

module parameter signal **924** corresponds to the sensor module parameter signal **832** (FIG. **8**), derived by the signal processor **830** (FIG. **8**).

Also shown in FIG. **9**, the waveform generator **930** is a particular embodiment of the waveform processor **730** (FIG. **7**) described above. The waveform generator **930** generates a synthesized waveform **932** that the pulse oximeter monitor **360** can process to calculate SpO_2 and pulse rate values or exception messages. In the present embodiment, the waveform generator output does not reflect a physiological waveform. In particular, the synthesized waveform is not physiological data from the sensor module **800**, but is a waveform synthesized from predetermined stored waveform data to cause the monitor **360** to calculate oxygen saturation and pulse rate equivalent to or generally equivalent (within clinical significance) to that calculated by the signal processor **830** (FIG. **8**). The actual intensity signal from the patient received by the detector **314** (FIG. **8**) is not provided to the monitor **360** in the present embodiment. Indeed, the waveform provided to the monitor **360** will usually not resemble a plethysmographic waveform or other physiological data from the patient to whom the sensor module **800** (FIG. **8**) is attached.

The synthesized waveform **932** is modulated according to the drive signal input **934**. That is, the pulse oximeter monitor **360** expects to receive a red and IR modulated intensity signal originating from a detector, as described with respect to FIGS. **1-2**, above. The waveform generator **930** generates the synthesized waveform **932** with a predetermined shape, such as a triangular or sawtooth waveform stored in waveform generator memory or derived by a waveform generator algorithm. The waveform is modulated synchronously with the drive input **934** with first and second amplitudes that are processed in the monitor **360** as red and IR portions of a sensor signal. The frequency and the first and second amplitudes are adjusted so that pulse rate and oxygen saturation measurements derived by the pulse oximeter monitor **360** are generally equivalent to the parameter measurements derived by the signal processor **830** (FIG. **8**), as described above. One embodiment of a waveform generator **930** is described in U.S. Patent Application No. 60/117,097 entitled "Universal/Upgrading Pulse Oximeter," assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein. Although the waveform generator **930** is described above as synthesizing a waveform that does not resemble a physiological signal, one of ordinary skill will recognize that another embodiment of the waveform generator **930** could incorporate, for example, a plethysmograph simulator or other physiological signal simulator.

Further shown in FIG. **9**, the interface cable **950** functions in a manner similar to the monitor interface **750** (FIG. **7**) described above. The interface cable **950** is configured to communicate the synthesized waveform **932** to the monitor **360** sensor port and to communicate the sensor drive signal **934** to the waveform generator **930**. The interface cable **950** may include a ROM **960** that contains monitor and sensor characterization data. The ROM **960** is read by the waveform generator **930** so that the synthesized waveform **932** is adapted to a particular monitor **360**. For example, the ROM **960** may contain calibration data of red/IR versus oxygen saturation, waveform amplitude and waveform shape information. An interface cable is described in U.S. Patent Application No. 60/117,092, referenced above. Monitor-specific SatShare™ brand interface cables are available from Masimo Corporation, Irvine, Calif. In an alternative embodiment, such as a direct connect monitor module as illustrated in FIG. **5**A, an interface cable **950** is not used and the ROM **960** may be incorporated within the monitor module **900** itself.

Plethysmograph Transmission

FIG. **10** illustrates another pulse oximetry sensor module **1000** having a sensor interface **1010**, encoder **1040**, transmitter **1050**, transmitting antenna **1070** and controller **1090**, which have the corresponding functions as those described with respect to FIG. **8**, above. The encoder **1040**, however, inputs a plethysmograph signal **1014** rather than oxygen saturation and pulse rate measurements **832** (FIG. **8**). Thus, the sensor module **1000** according to this embodiment encodes and transmits a plethysmograph signal **1014** to a corresponding monitor module **1100** (FIG. **11**) in contrast to derived physiological parameters, such as oxygen saturation and pulse rate. The plethysmograph signal **1014** is illustrated in FIG. **10** as being a direct output from the sensor interface **1010**. In another embodiment, the sensor module **1000** incorporates a decimation processor, not shown, after the sensor interface **1010** so as to provide a plethysmograph signal **1014** having a reduced sample rate.

FIG. **11** illustrates another pulse oximetry monitor module **1100** having a receive antenna **1170**, a receiver **1110**, a decoder **1120** and an interface cable **1150**, which have the corresponding functions as those described with respect to FIG. **9**, above. This monitor module embodiment **1100**, however, has a waveform modulator **1200** rather than a waveform generator **930** (FIG. **9**), as described above. The waveform modulator **1200** inputs a plethysmograph signal from the decoder **1120** rather than oxygen saturation and pulse rate measurements, as described with respect to FIG. **9**, above. Further, the waveform modulator **1200** provides an modulated waveform **1132** to the pulse oximeter monitor **360** rather than a synthesized waveform, as described with respect to FIG. **9**. The modulated waveform **1132** is a plethysmographic waveform modulated according to the monitor drive signal input **1134**. That is, the waveform modulator **1200** does not synthesize a waveform, but rather modifies the received plethysmograph signal **1124** to cause the monitor **360** to calculate oxygen saturation and pulse rate generally equivalent (within clinical significance) to that derivable by a compatible, calibrated pulse oximeter directly from the sensor signal **1012** (FIG. **10**). The waveform modulator **1200** is described in further detail with respect to FIG. **12**, below.

FIG. **12** shows a waveform modulator **1200** having a demodulator **1210**, a red digital-to-analog converter (DAC) **1220**, an IR DAC **1230**, a red amplifier **1240**, an IR amplifier **1250**, a modulator **1260**, a modulator control **1270**, a look-up table (LUT) **1280** and a ratio calculator **1290**. The waveform modulator **1200** demodulates red and IR plethysmographs ("pleths") from the decoder output **1124** into a separate red pleth **1222** and IR pleth **1232**. The waveform modulator **1200** also adjusts the amplitudes of the pleths **1222**, **1232** according to stored calibration curves for the sensor **310** (FIG. **10**) and the monitor **360** (FIG. **11**). Further, the waveform modulator **1200** re-modulates the adjusted red pleth **1242** and adjusted IR pleth **1252**, generating a modulated waveform **1132** to the monitor **360** (FIG. **11**).

As shown in FIG. **12**, the demodulator **1210** performs the demodulation function described above, generating digital red and IR pleth signals **1212**, **1214**. The DACs **1220**, **1230** convert the digital pleth signals **1212**, **1214** to corresponding analog pleth signals **1222**, **1232**. The amplifiers **1240**, **1250** have variable gain control inputs **1262**, **1264** and perform the amplitude adjustment function described above, generating adjusted red and IR pleth signals **1242**, **1252**. The

modulator **1260** performs the re-modulation function described above, combining the adjusted red and IR pleth signals **1242**, **1252** according to a control signal **1272**. The modulator control **1270** generates the control signal **1272** synchronously with the LED drive signal(s) **1134** from the monitor **360**.

Also shown in FIG. **12**, the ratio calculator **1290** derives a red/IR ratio from the demodulator outputs **1212**, **1214**. The LUT **1280** stores empirical calibration data for the sensor **310** (FIG. **10**). The LUT **1280** also downloads monitor-specific calibration data from the ROM **1160** (FIG. **11**) via the ROM output **1158**. From this calibration data, the LUT **1280** determines a desired red/IR ratio for the modulated waveform **1132** and generates red and IR gain outputs **1262**, **1264** to the corresponding amplifiers **1240**, **1250**, accordingly. A desired red/IR ratio is one that allows the monitor **360** (FIG. **11**) to derive oxygen saturation measurements from the modulated waveform **1132** that are generally equivalent to that derivable directly from the sensor signal **1012** (FIG. **10**).

One of ordinary skill in the art will recognize that some of the signal processing functions described with respect to FIGS. **8-11** may be performed either within a sensor module or within a monitor module. Signal processing functions performed within a sensor module may advantageously reduce the transmission bandwidth to a monitor module at a cost of increased sensor module size and power consumption. Likewise, signal processing functions performed within a monitor module may reduce sensor module size and power consumption at a cost of increase transmission bandwidth.

For example, a monitor module embodiment **900** (FIG. **9**) described above receives measured pulse oximeter parameters, such as oxygen saturation and pulse rate, and generates a corresponding synthesized waveform. In that embodiment, the oxygen saturation and pulse rate computations are performed within a sensor module **800** (FIG. **8**). Another monitor module embodiment **1100** (FIG. **11**), also described above, receives a plethysmograph waveform and generates a remodulated waveform. In that embodiment, minimal signal processing is performed within a sensor module **1000** (FIG. **10**). In yet another embodiment, not shown, a sensor module transmits a plethysmograph waveform or a decimated plethysmograph waveform having a reduced sample rate. A corresponding monitor module has a signal processor, such as described with respect to FIG. **8**, in addition to a waveform generator, as described with respect to FIG. **9**. The signal processor computes pulse oximeter parameters and the waveform generator generates a corresponding synthesized waveform, as described above. In this embodiment, minimal signal processing is performed within the sensor module, and the monitor module functions are performed on the pulse oximeter parameters computed within the monitor module.

Wireless Multiple Parameter Measurements

FIGS. **13-14** illustrate a multiple parameter communications adapter. FIG. **13** illustrates a multiple parameter sensor module **1300** having sensor interfaces **1310**, one or more signal processors **1330**, a multiplexer and encoder **1340**, a transmitter **1350**, a transmitting antenna **1370** and a controller **1390**. One or more physiological sensors **1301** provide input sensor signals **1312** to the sensor module **1300**. Depending on the particular sensors **1301**, the sensor module **1300** may provide one or more drive signals **1312** to the sensors **1301** as determined by the controller **1390**. The sensor interfaces **1310** input the sensor signals **1312** and output one or more conditioned signals **1314**. The conditioned signals **1314** may be coupled to the transmitter **1350** or further processed by the signal processors **1330**. If the sensor module configuration utilizes signal processors **1330**, it derives multiple parameter signals **1332** responsive to the sensor signals **1312**, which are then coupled to the transmitter **1350**. Regardless, the transmitter **1350** inputs a baseband signal **1342** that is responsive to the sensor signals **1312**. The transmitter **1350** modulates the baseband signal **1342** with a carrier to generate a transmit signal **1354**, which is coupled to the transmit antenna **1370** and communicated to a corresponding receive antenna **1470** (FIG. **14**), as described with respect to FIG. **6**, above. Alternatively, there may be multiple baseband signals **1342**, and the transmitter **1350** may transmit on multiple frequency channels, where each channel coveys data responsive to one or more of the sensor signals **1314**.

As shown in FIG. **13**, the sensor interface **1310** conditions and digitizes the sensor signals **1312** as described for a single sensor with respect to FIG. **6**, above. The resulting conditioned signals **1314** are responsive to the sensor signals **1312**. The signal processors **1330** perform signal processing on the conditioned signals **1314** to derive parameter signals **1332**, as described for a single conditioned signal with respect to FIG. **6**, above. The parameter signals **1332** may be physiological measurements such as oxygen saturation, pulse rate, blood glucose, blood pressure, EKG, respiration rate and body temperature to name a few, or may be intermediate results from which the above-stated measurements may be calculated or derived. The multiplexer and encoder **1340** combines multiple digital word or serial bit streams into a single digital word or bit stream. The multiplexer and encoder also encodes the digital word or bit stream to generate the baseband signal **1342**, as described with respect to FIG. **6**, above.

FIG. **14** illustrates a multiple parameter monitor module **1400** having a receive antenna **1470**, a receiver **1410**, a demultiplexer and decoder **1420**, one or more waveform processors **1430** and a monitor interface **1450**. The receiver **1410** inputs and demodulates the receive signal **1412** corresponding to the transmit signal **1354** (FIG. **13**) to generate a baseband signal **1414** as described with respect to FIG. **7**, above. The demultiplexer and decoder **1420** separates the symbol streams corresponding to the multiple conditioned signals **1314** (FIG. **13**) and/or parameter signals **1332** (FIG. **13**) and translates these symbol streams into multiple decoded signals **1422**, as described for a single symbol stream with respect to FIG. **7**, above. Alternatively, multiple frequency channels are received to generate multiple baseband signals, each of which are decoded to yield multiple decoded signals **1422**. The waveform processors **1430** input the decoded signals **1422** and generate multiple constructed signals **1432**, as described for a single decoded signal with respect to FIGS. **7-12**, above. The monitor interface **1450** is configured to communicate the constructed signals **1432** to the sensor ports of a multiple parameter monitor **1401** or multiple single parameter monitors, in a manner similar to that for a single constructed signal, as described with respect to FIGS. **7-12**, above. In particular, the constructed signals **1432** are adapted to the monitor **1401** so that measurements derived by the monitor **1401** from the constructed signals **1432** are generally equivalent to measurements derivable directly from the sensor signals **1312** (FIG. **13**).

A physiological measurement communications adapter is described above with respect to wireless communications and, in particular, radio frequency communications. A sensor module and monitor module, however, may also communicate via wired communications, such as telephone, Internet

or fiberoptic cable to name a few. Further, wireless communications can also utilize light frequencies, such as IR or laser to name a few.

A physiological measurement communications adapter has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only. One of ordinary skill in the art will appreciate many variations and modifications of a physiological measurement communications adapter within the scope of the claims that follow.

What is claimed is:

1. A wearable, portable physiological monitor configured to wirelessly transmit real time information regarding a plurality physiological parameters, the portable monitor comprising:

a plurality of sensor ports positioned on a housing of the portable monitor and configured to provide respective wired interfaces with different respective physiological sensors of a plurality of physiological sensors, wherein:

at least a first sensor port of the plurality of sensor ports is positioned on a side of the housing of the portable monitor such that, when the portable monitor is attached to an arm of a patient, a wired connection extending from the first sensor port to a first physiological sensor positioned on a digit of the patient follows a path to the digit of the patient that is substantially perpendicular to the side of the housing and avoids tangling of the wired connection;

one or more processing devices configured to:

receive, via the plurality of sensor ports, a plurality of signals from the plurality of physiological sensors, at least some of the plurality of signals including digital information, and at least some of the plurality of signals including analog information;

cause to be displayed, on a display of the portable monitor, a plurality of physiological parameters values responsive to the plurality of signals;

combine information indicative of the plurality of signals into a single digital word or bit stream; and

encode the single digital word or bit stream to generate a baseband signal; and

a transmitter configured to:

modulate the baseband signal with a carrier to generate a transmit signal; and

wirelessly transmit the transmit signal to a remote patient monitoring device configured to decode the signal and display, on a remote display, the plurality of physiological parameters values responsive to the plurality of signals.

2. The portable monitor of claim **1**, wherein the one or more processing devices are further configured to:

process, at least in part in the analog domain, at least a first signal of the plurality of signals to determine at least a first one or more of the plurality of physiological parameters values; and

process, at least in part in the digital domain, at least a second signal of the plurality of signals to determine at least a second one or more of the plurality of physiological parameters values.

3. The portable monitor of claim **2**, wherein the first signal is received via the first sensor port from the first physiological sensor.

4. The portable monitor of claim **3**, wherein the first physiological sensor comprises a pulse oximetry sensor.

5. The portable monitor of claim **4**, wherein the first one or more of the plurality of physiological parameters values comprises at least oxygen saturation and pulse rate.

6. The portable monitor of claim **2**, wherein the one or more processing devices comprise:

a multiplexer configured to combine the information indicative of the plurality of signals into the single digital word or bit stream; and

an encoder configured to encode the single digital word or bit stream to generate the baseband signal.

7. The portable monitor of claim **6**, wherein the baseband signal comprises a single signal.

8. The portable monitor of claim **6**, wherein the baseband signal comprises multiple related signal components including at least one of: in-phase signals or quadrature signals.

9. The portable monitor of claim **6**, wherein the transmitter is further configured to transmit on multiple frequency channels.

10. The portable monitor of claim **1**, wherein the plurality of sensor ports comprise at least:

a second sensor port configured to receive a signal from an EKG sensor arrangement; and

a third sensor port configured to receive a signal from a blood pressure sensor arrangement.

11. The portable monitor of claim **10** further comprising:

a plurality of sensor interfaces configured to receive the plurality of signals and initially process the plurality of signals, wherein:

each of the plurality of sensor interfaces is associated with a respective sensor port of the plurality of sensor ports, and

each of the plurality of sensor interfaces is configured to receive a signal from a respective physiological sensor of the plurality of physiological sensors.

12. The portable monitor of claim **1**, wherein a face of the housing comprises a single user interface, and the face of the housing is viewable by a user when the portable monitor is attached to the arm of the patient.

13. The portable monitor of claim **12**, wherein the single user interface comprises the display.

14. The portable monitor of claim **13**, wherein the display is positioned centrally on the face of the housing.

15. The portable monitor of claim **14**, wherein the display positioned on the face of the housing is sized such that the display covers more than half of a length of a shortest dimension of the face of the housing.

16. A battery-powered wearable physiological monitoring device configured to communicate with multiple types of sensor arrangements via a plurality of sensor interfaces, the wearable physiological monitoring device comprising:

a plurality of sensor communication ports including:

a first sensor communication port configured to provide wired communication with a first type of physiological sensor arrangement, wherein the first sensor port is positioned on the device such that a wire extending from the first sensor communication port to the first type of physiological sensor arrangement extends from the device along an axis perpendicular to a face of the device upon which the first sensor port is positioned;

a second sensor communication port configured to provide wired communication with a second type of physiological sensor arrangement different from the first type of physiological sensor arrangement; and

a third sensor communication port configured to provide wired communication with a third type of physiological sensor arrangement different from both the first and second types of physiological sensor arrangements;

a plurality of sensor interfaces including:

a first sensor interface configured to receive a first signal from a first sensor arrangement of the first type, the first signal including analog information;

a second sensor interface configured to receive a second signal from a second sensor arrangement of the second type the second signal including digital information; and

a third sensor interface configured to receive a third signal from a third sensor arrangement of the third type;

wherein the plurality of sensor interfaces are configured to output one or more signals indicative of physiological parameters sensed by the first, second, and third sensor arrangements;

a display positioned on a face of the wearable physiological monitoring device configured to display information while the wearable physiological monitoring device is being worn by a patient;

a processor configured to:

responsive to the one or more signals indicative of the physiological parameters, cause to be displayed, on the display, physiological parameter measurements;

combine information indicative of the one or more signals into a single digital word or bit stream; and

encode the single digital word or bit stream to generate a baseband signal;

a transmitter configured to:

modulate the baseband signal with a carrier to generate a transmit signal; and

wirelessly transmit the transmit signal to a receiving patient monitoring device that is not wired to the wearable physiological monitoring device; and

a battery configured to provide power to at least the processor, the display, the transmitter, and the first sensor arrangement via the first sensor communication port such that the wearable physiological monitoring device is portable and wearable by a patient.

17. The wearable physiological monitoring device of claim **16**, wherein:

at least one of the first, second, or third sensor interfaces is configured to process signals at least in part in the analog domain; and

at least at different one of the first, second, or third sensor interfaces is configured to process signals at least in part in the digital domain.

18. The wearable physiological monitoring device of claim **17**, wherein the first sensor arrangement comprises a pulse oximetry sensor configured to be attached to a digit of a patient.

19. The wearable physiological monitoring device of claim **18**, wherein the first sensor port is positioned on a side of the wearable physiological monitoring device that faces a hand of a patient when the wearable physiological monitoring device is attached to an arm of the hand of the patient.

20. The wearable physiological monitoring device of claim **19**, wherein the face of the wearable physiological monitoring device comprises a single user interface, and the single user interface comprises the display.

* * * * *

US009872623B2

(12) **United States Patent**
Al-Ali

(10) **Patent No.: US 9,872,623 B2**
(45) **Date of Patent: *Jan. 23, 2018**

(54) **ARM MOUNTABLE PORTABLE PATIENT MONITOR**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 9 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/494,967**

(22) Filed: **Apr. 24, 2017**

(65) **Prior Publication Data**

US 2017/0224231 A1 Aug. 10, 2017

Related U.S. Application Data

(63) Continuation of application No. 15/448,989, filed on Mar. 3, 2017, which is a continuation of application (Continued)

(51) **Int. Cl.**
A61B 5/1455 (2006.01)
A61B 5/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/0205*** (2013.01); ***A61B 5/0004*** (2013.01); ***A61B 5/6824*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC ... A61B 5/0002; A61B 5/0004; A61B 5/0024; A61B 5/02; A61B 5/0205; A61B 5/0402;
(Continued)

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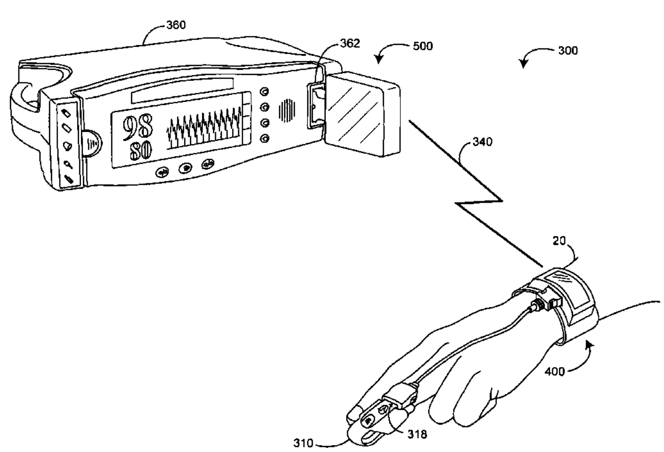
(57) **ABSTRACT**

An arm mountable portable patient monitoring device configured for both on patient monitoring of parameter measurements using one or more sensors operatively connected to the portable patient monitoring device and wireless transmission of parameter measurements. The arm mountable portable patient monitoring device includes a pulse oximetry sensor configured to be wrapped around a digit of a patient, a housing having a size and shape configured for mounting to a lower arm of the patient, and a strap mountable to the back side of the housing and configured to secure the housing to the lower arm of the patient. The housing includes a display, a first sensor port positioned on the housing to face toward a hand of the patient, second and third sensor ports, a battery, signal processing arrangements to cause display of parameter measurements, and a transmitter to transmit information indicative of the measurements.

20 Claims, 17 Drawing Sheets



Related U.S. Application Data

No. 14/815,232, filed on Jul. 31, 2015, now abandoned, which is a continuation of application No. 14/217,788, filed on Mar. 18, 2014, now Pat. No. 9,113,832, which is a continuation of application No. 14/037,137, filed on Sep. 25, 2013, now Pat. No. 9,113,831, which is a continuation of application No. 12/955,826, filed on Nov. 29, 2010, now Pat. No. 8,548,548, which is a continuation of application No. 11/417,006, filed on May 3, 2006, now Pat. No. 7,844,315, which is a continuation of application No. 11/048,330, filed on Feb. 1, 2005, now Pat. No. 7,844,314, which is a continuation of application No. 10/377,933, filed on Feb. 28, 2003, now Pat. No. 6,850,788.

(60) Provisional application No. 60/367,428, filed on Mar. 25, 2002.

(51) **Int. Cl.**
A61B 5/0205 (2006.01)
A61B 5/0402 (2006.01)
A61B 5/021 (2006.01)
A61B 5/024 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 5/6826*** (2013.01); ***A61B 5/6831*** (2013.01); ***A61B 5/7271*** (2013.01); *A61B 5/021* (2013.01); *A61B 5/02438* (2013.01); *A61B 5/0402* (2013.01); *A61B 5/14552* (2013.01)

(58) **Field of Classification Search**
CPC . A61B 5/1455; A61B 5/14551; A61B 5/6825; A61B 5/6826; A61B 5/6831; A61B 5/72; A61B 2560/0043; A61B 2562/06
See application file for complete search history.

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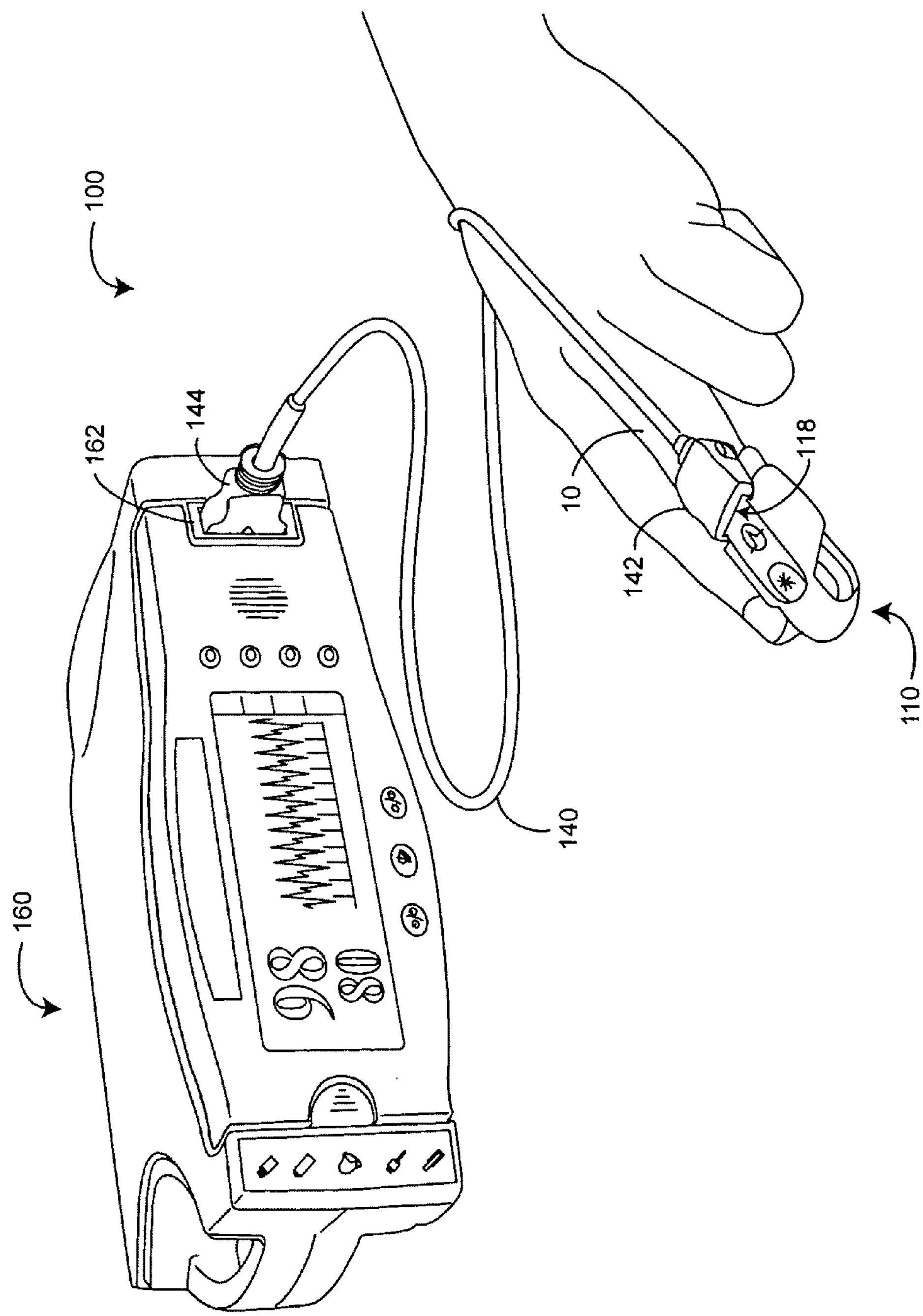

FIG. 1 (Prior Art)

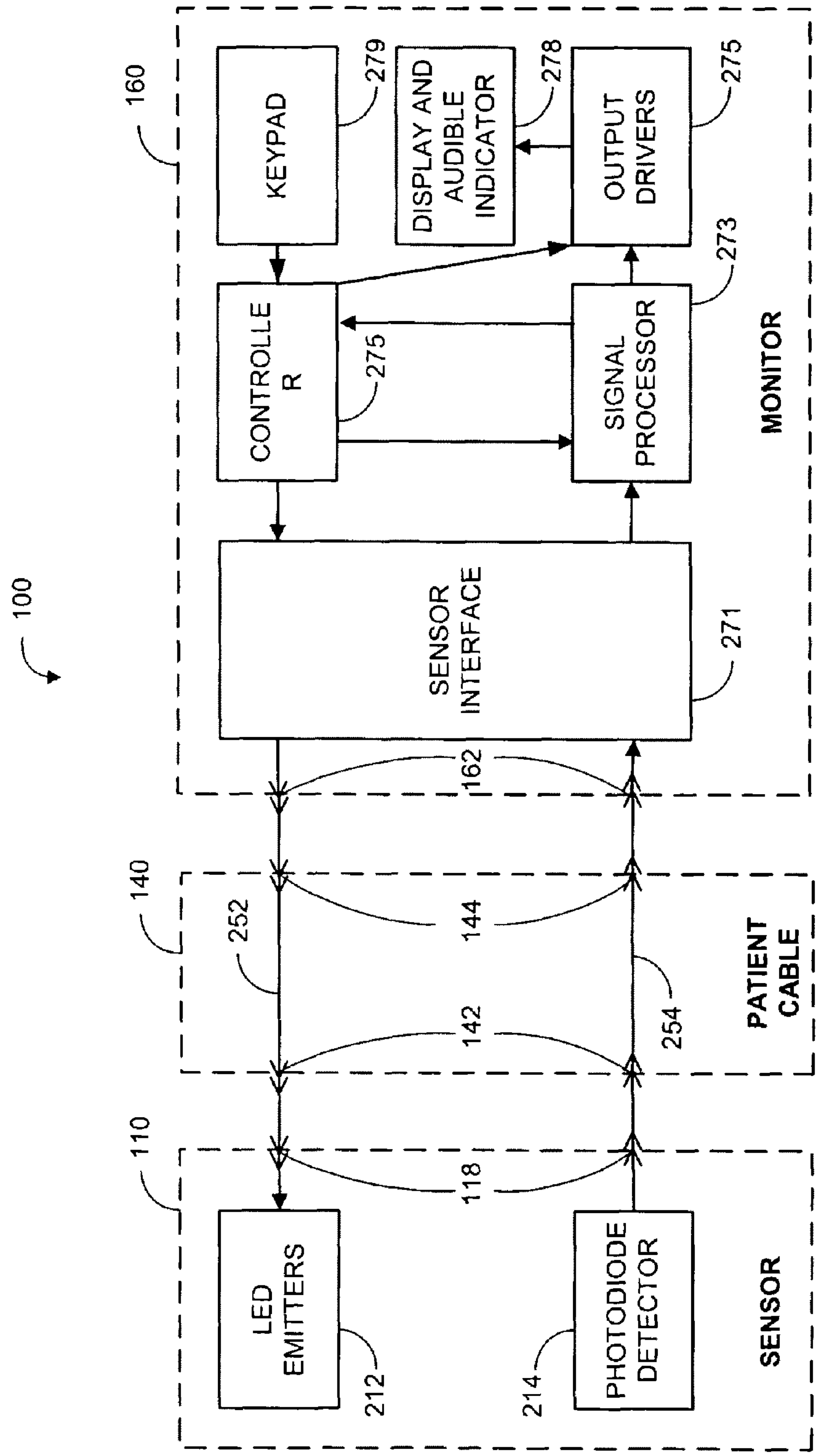

FIG. 2 (Prior Art)

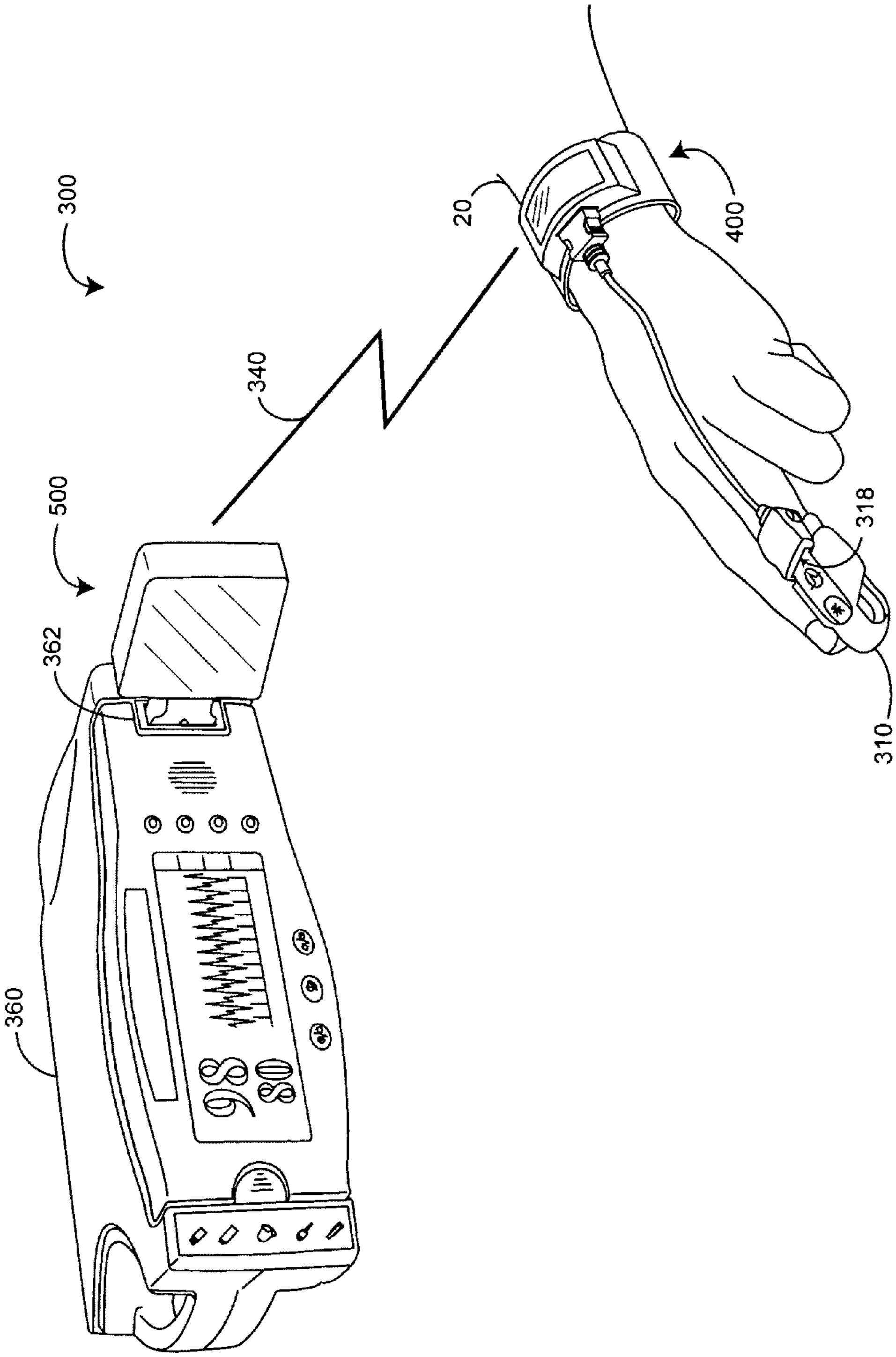

FIG. 3

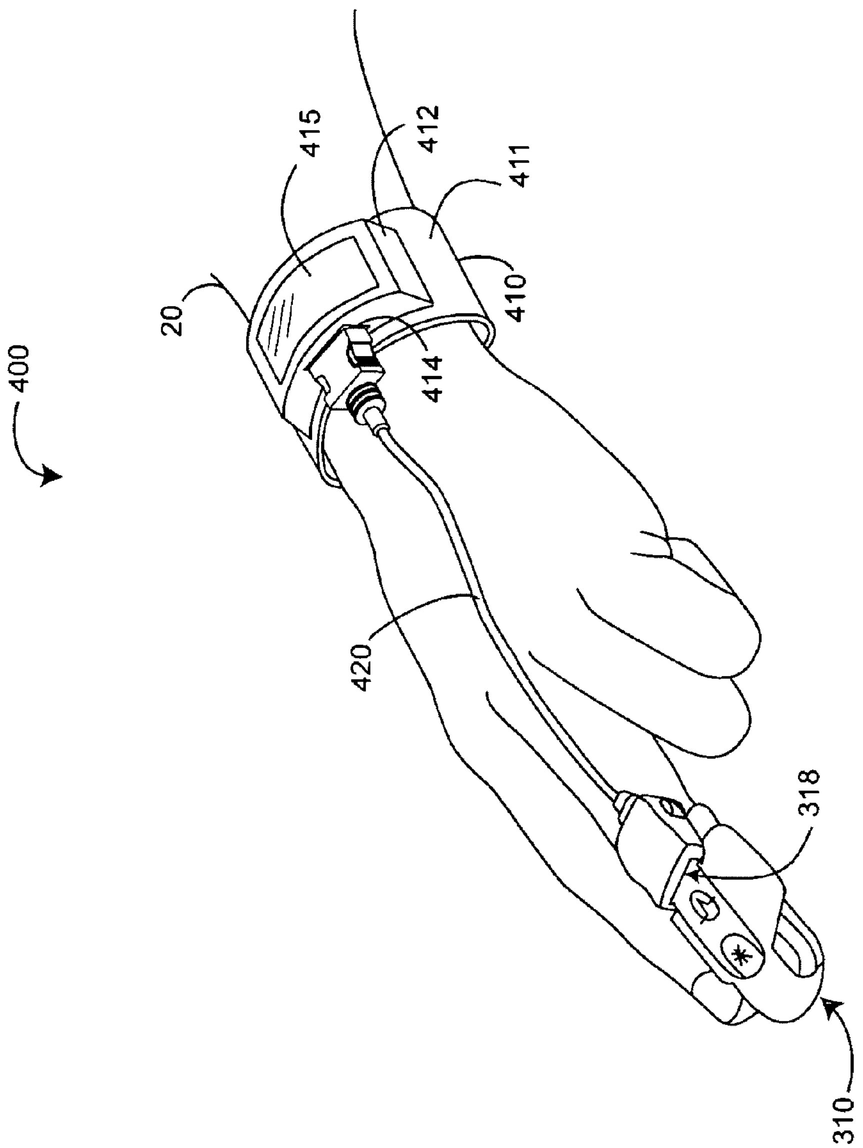

FIG. 4A

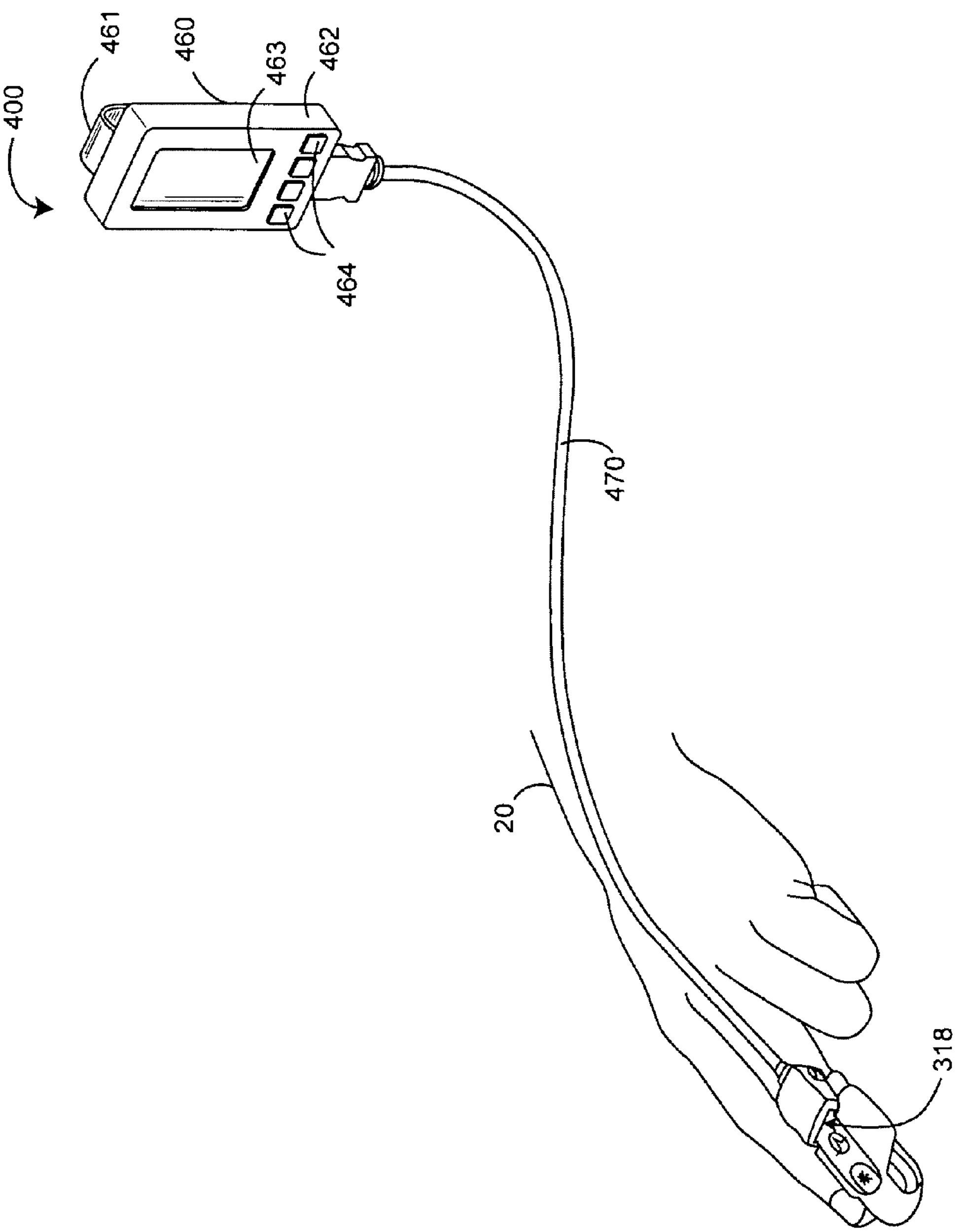

FIG. 4B

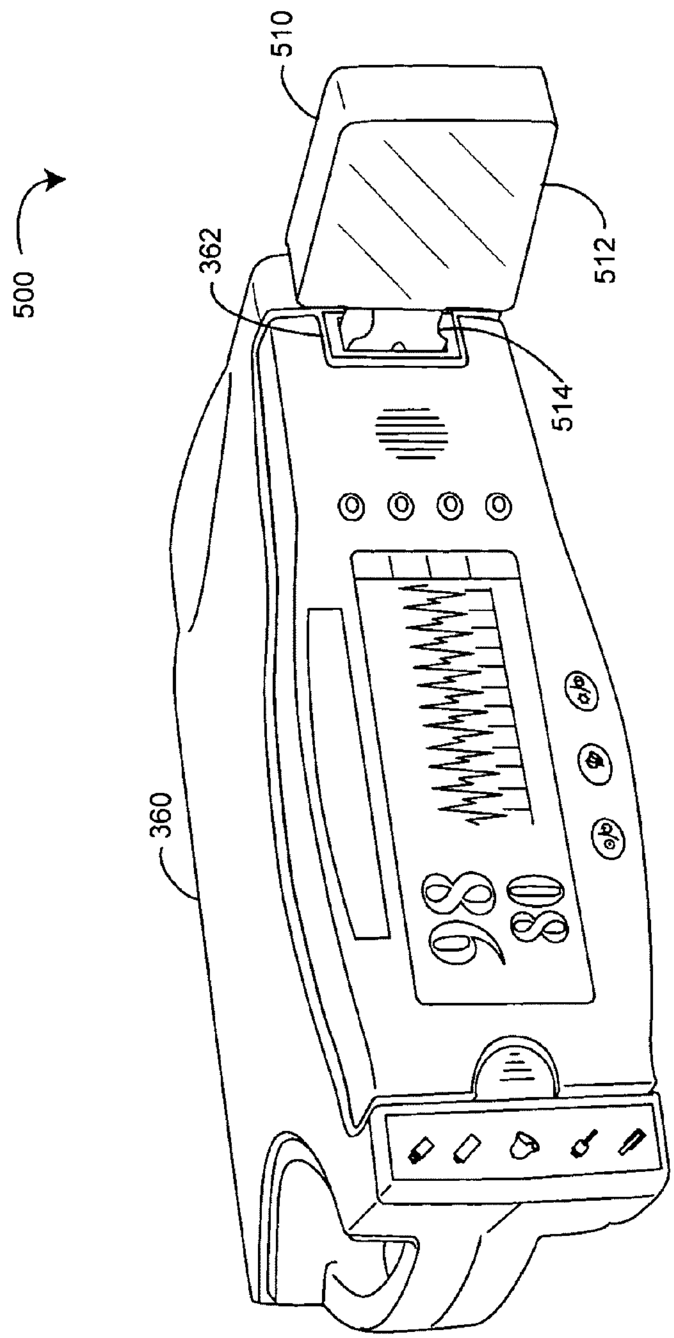

FIG. 5A

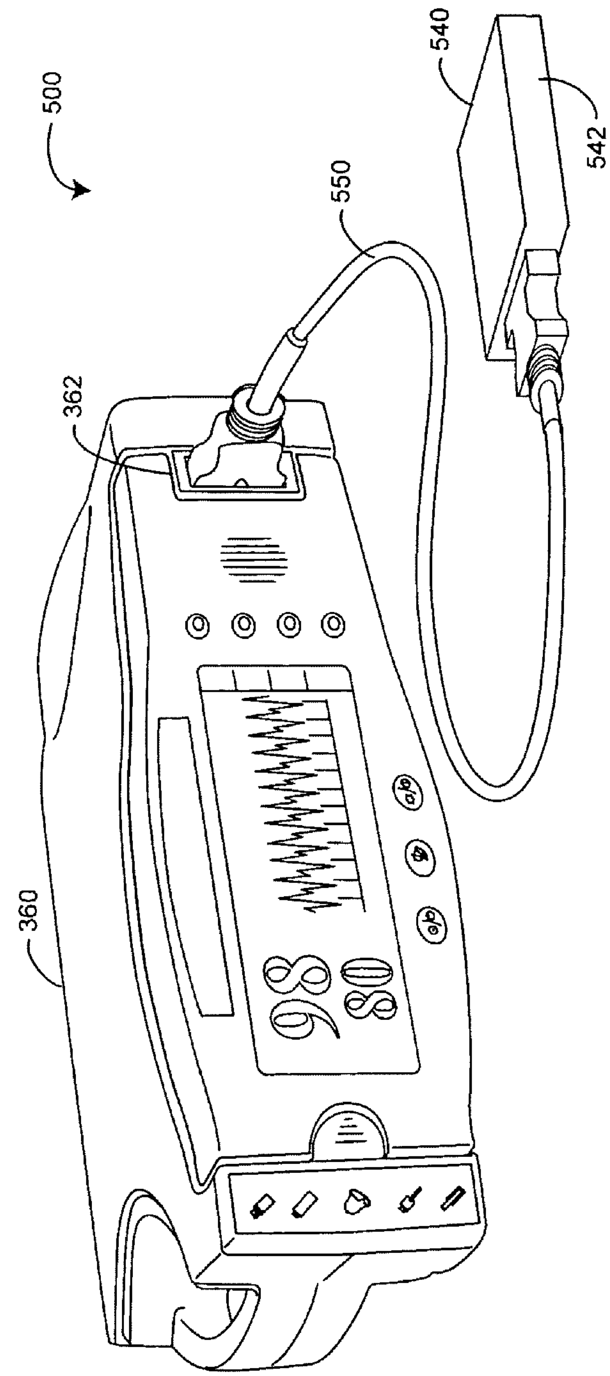

FIG. 5B

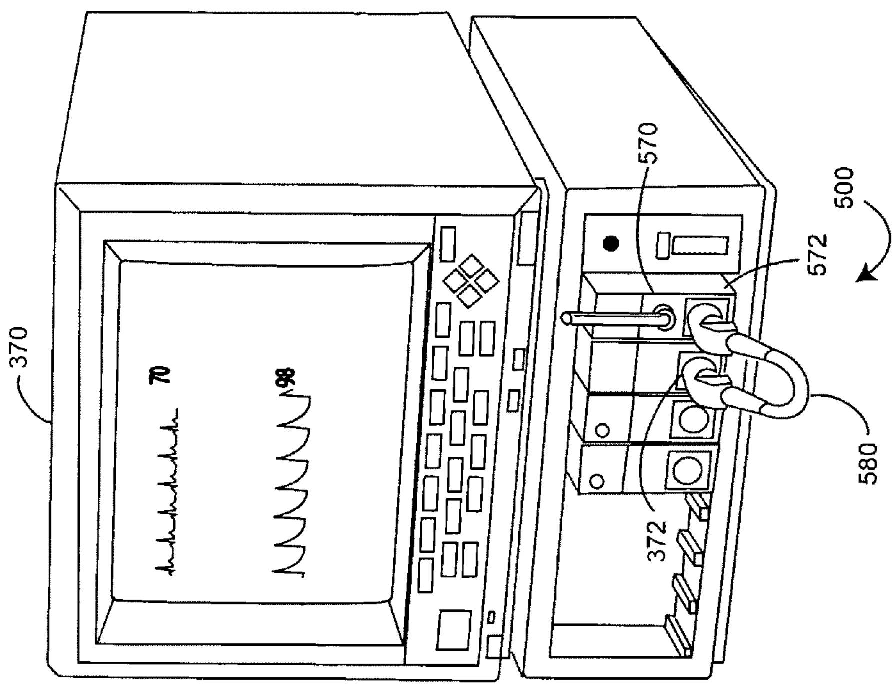

FIG. 5C

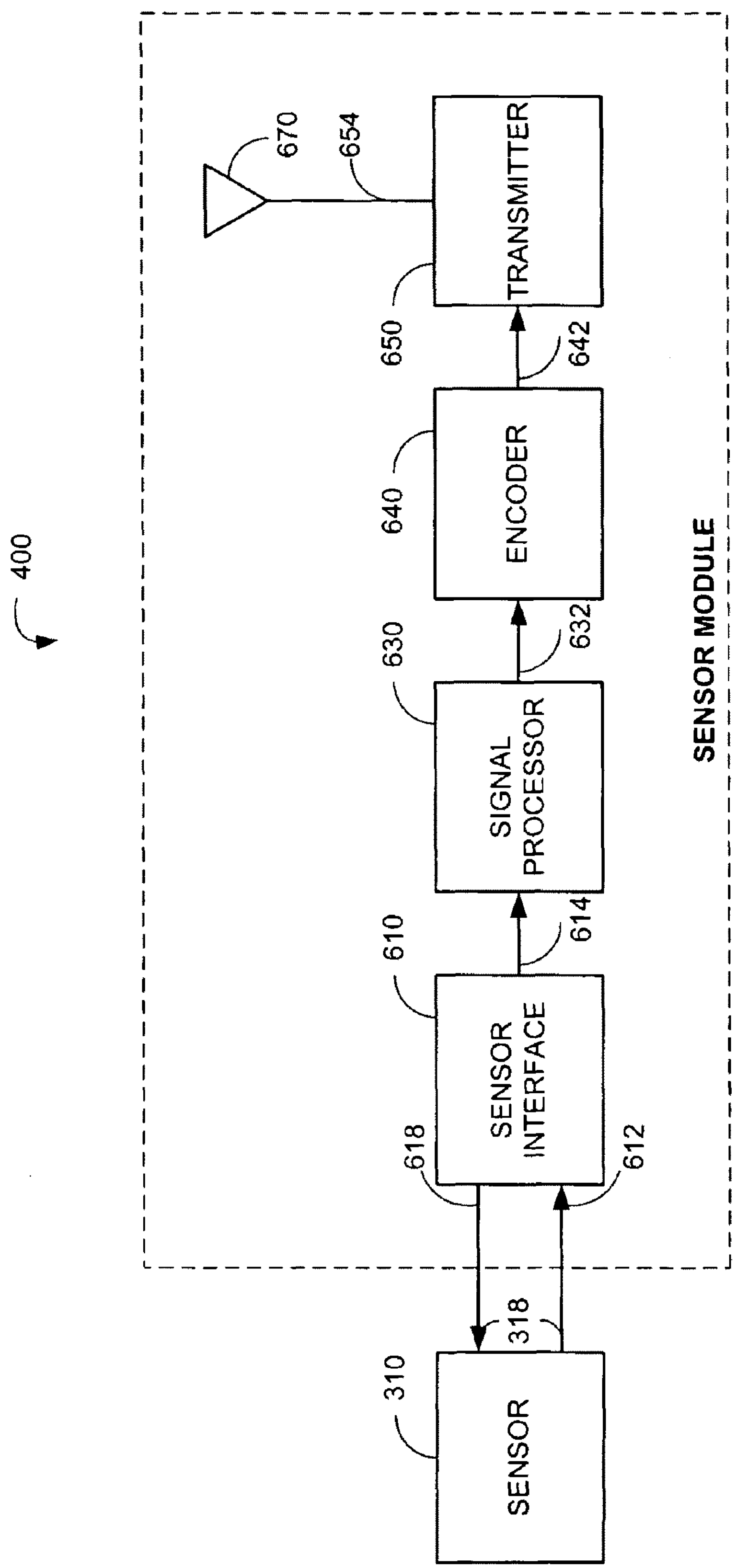
400
670
654
TRANSMITTER
650
642
ENCODER
640
632
SIGNAL PROCESSOR
630
614
SENSOR INTERFACE
610
618
612
SENSOR MODULE
318
SENSOR
310

FIG. 6

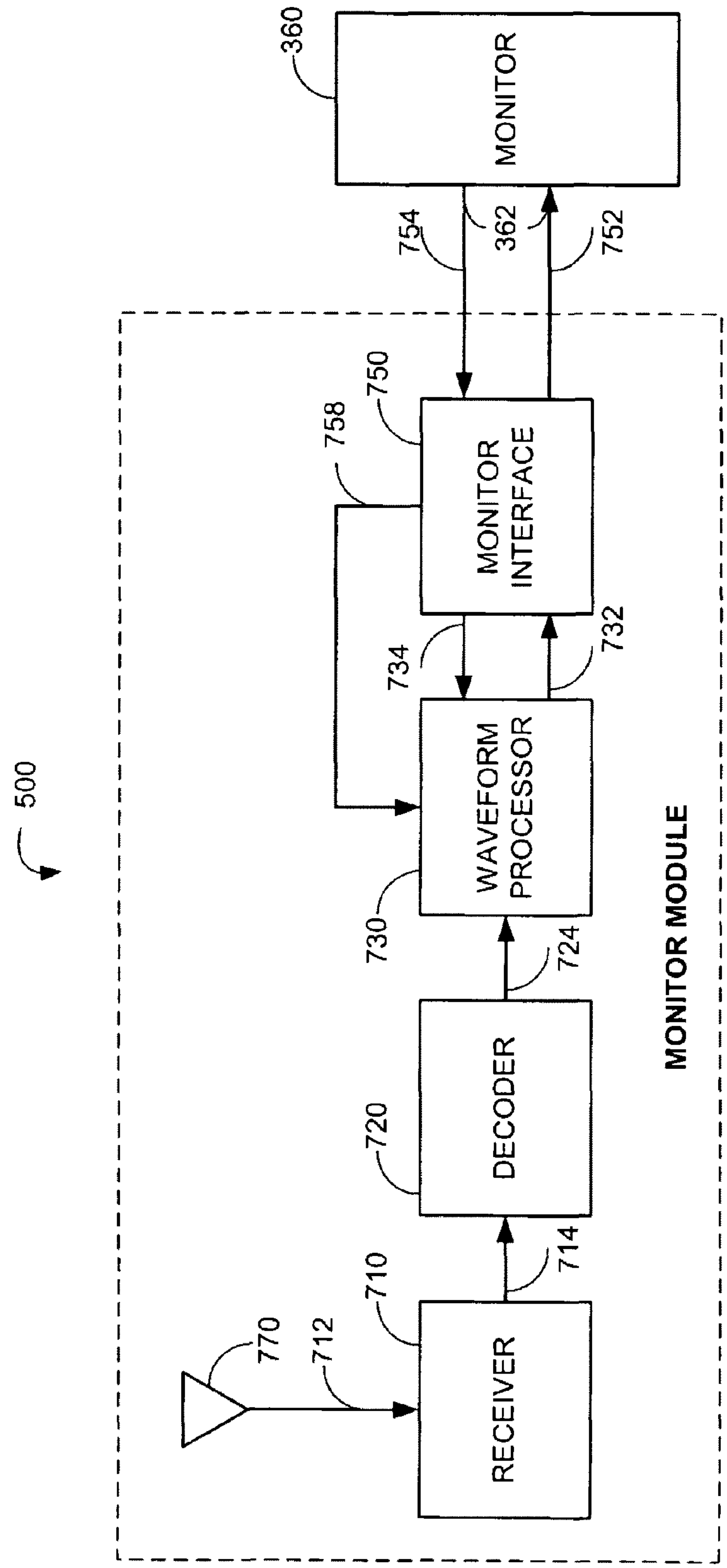
500
360
MONITOR
754
362
752
750
758
MONITOR INTERFACE
734
732
WAVEFORM PROCESSOR
730
724
DECODER
720
714
RECEIVER
710
770
712
MONITOR MODULE

FIG. 7

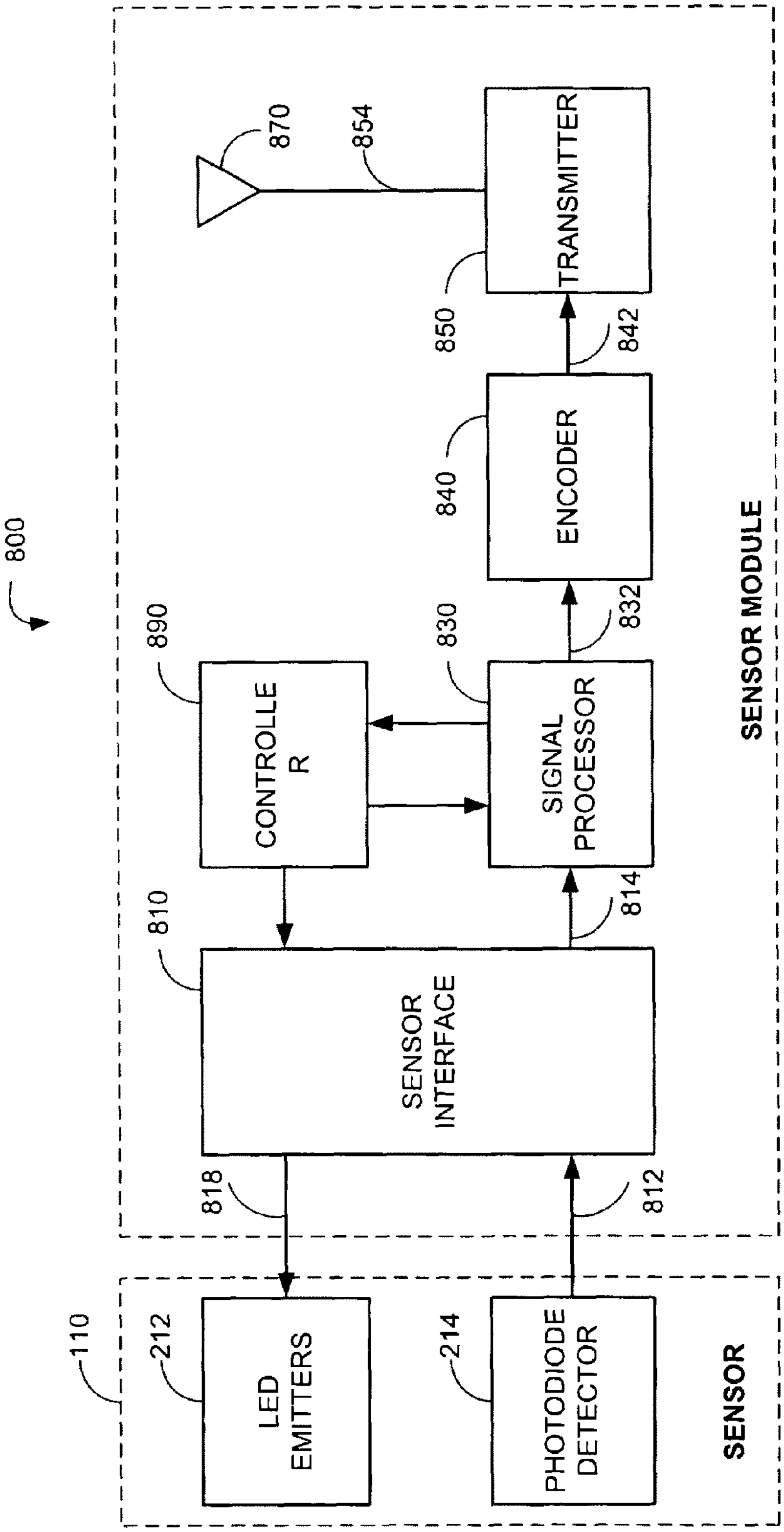
800
870
854
850
TRANSMITTER
842
840
ENCODER
832
830
890
CONTROLLE R
SIGNAL PROCESSOR
810
814
SENSOR INTERFACE
818
812
SENSOR MODULE
110
212
LED EMITTERS
214
PHOTODIODE DETECTOR
SENSOR

FIG. 8

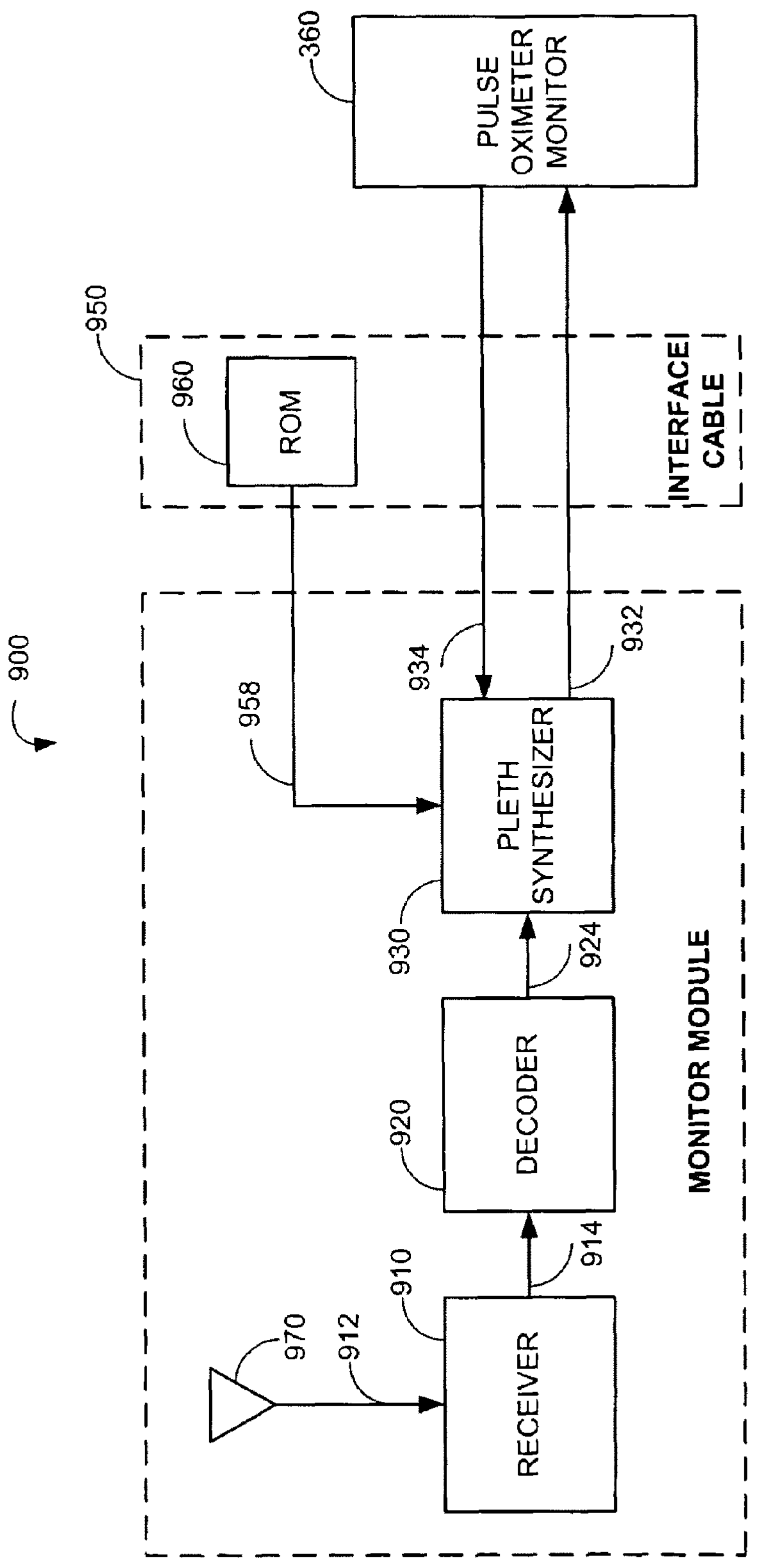
900
PULSE OXIMETER MONITOR
360
950
960
ROM
INTERFACE CABLE
934
932
958
PLETH SYNTHESIZER
930
924
DECODER
920
914
910
970
912
RECEIVER
MONITOR MODULE

FIG. 9

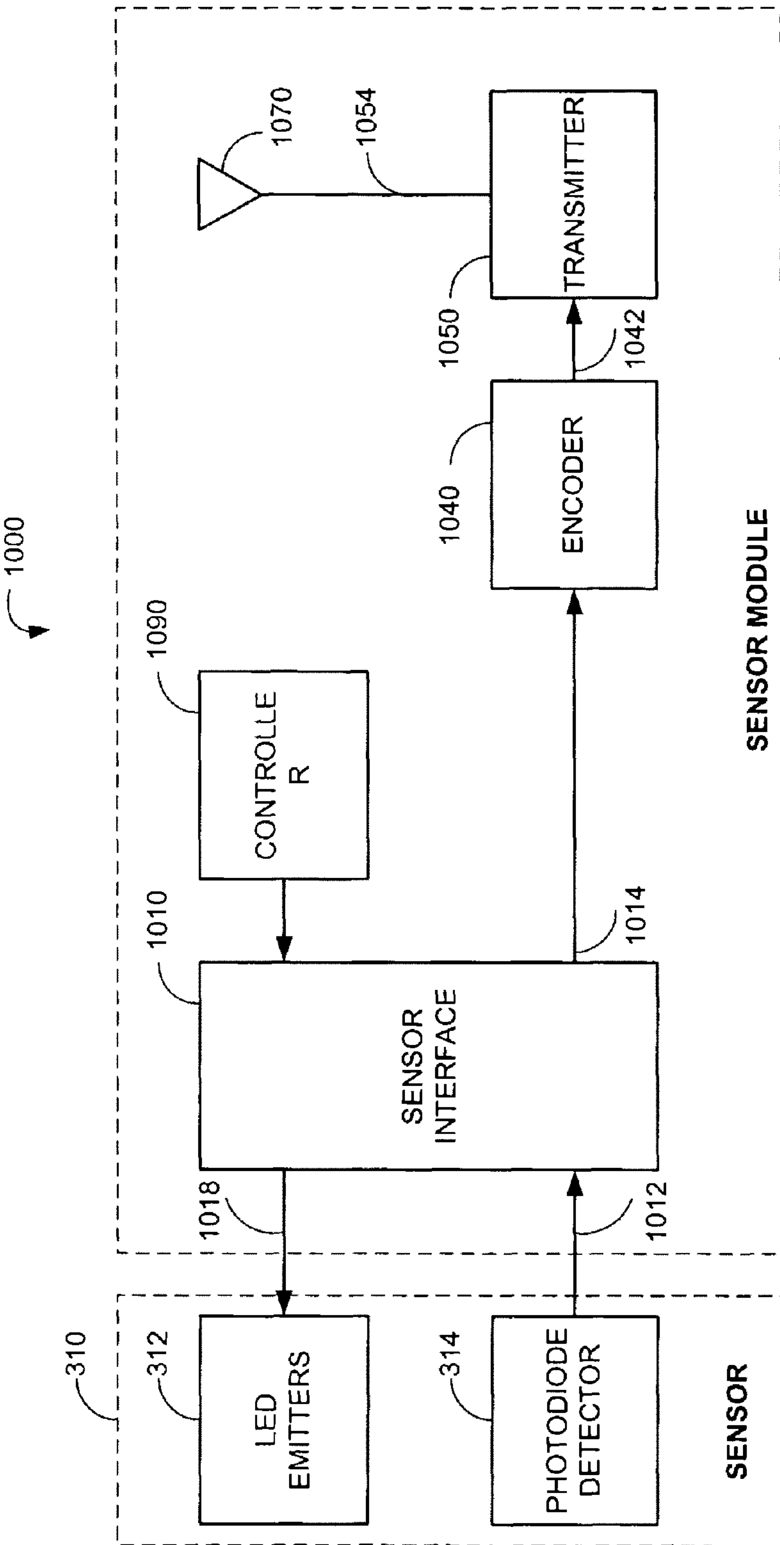
1000
1070
1054
TRANSMITTER
1050
1042
ENCODER
1040
1090
CONTROLLE
R
1010
1014
SENSOR
INTERFACE
SENSOR MODULE
1018
1012
310
312
LED
EMITTERS
314
PHOTODIODE
DETECTOR
SENSOR

FIG. 10

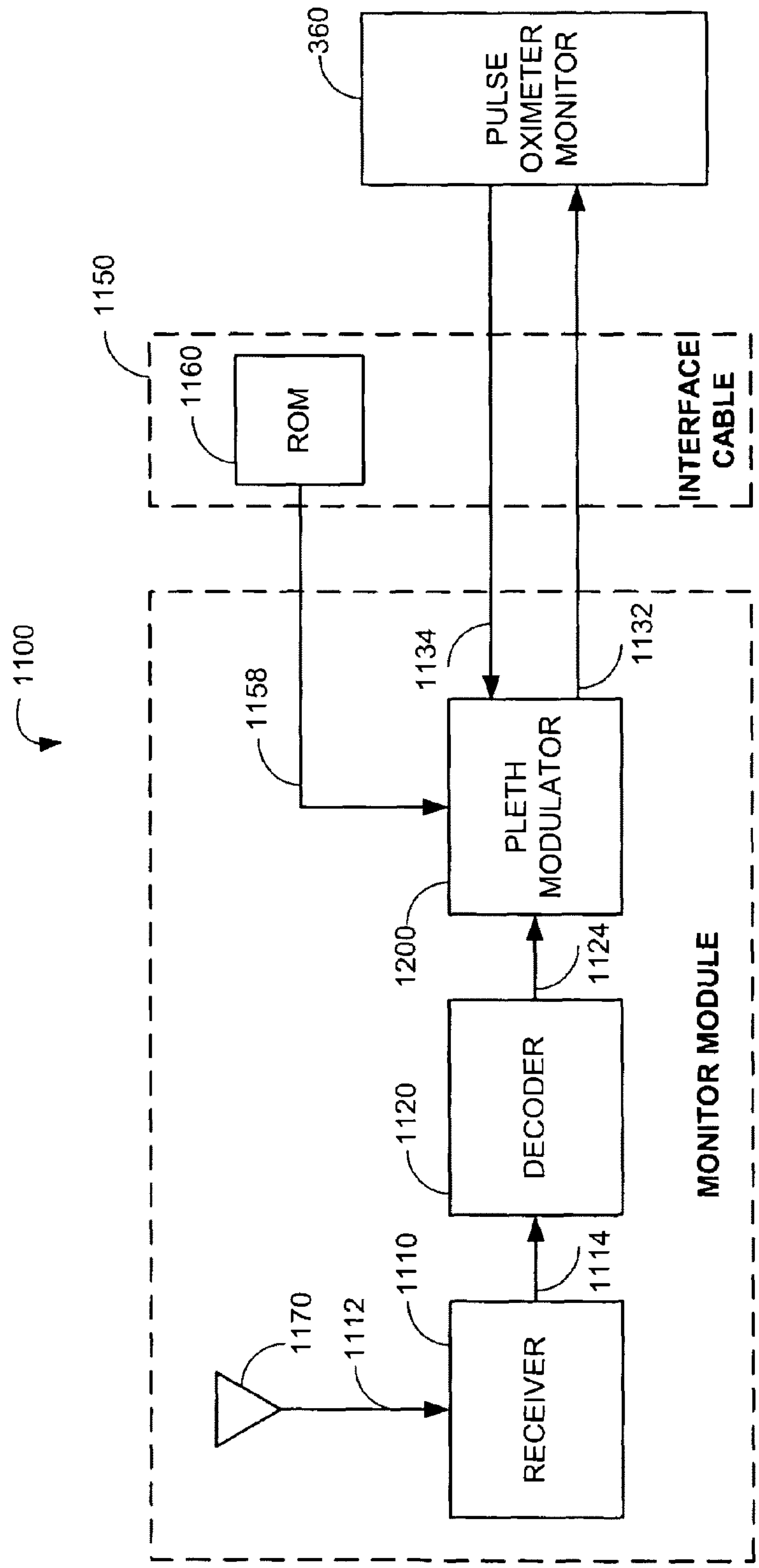
1100
360
PULSE OXIMETER MONITOR
1150
1160
ROM
INTERFACE CABLE
1158
1134
1132
PLETH MODULATOR
1200
1124
DECODER
1120
1114
1110
RECEIVER
1112
1170
MONITOR MODULE

FIG. 11

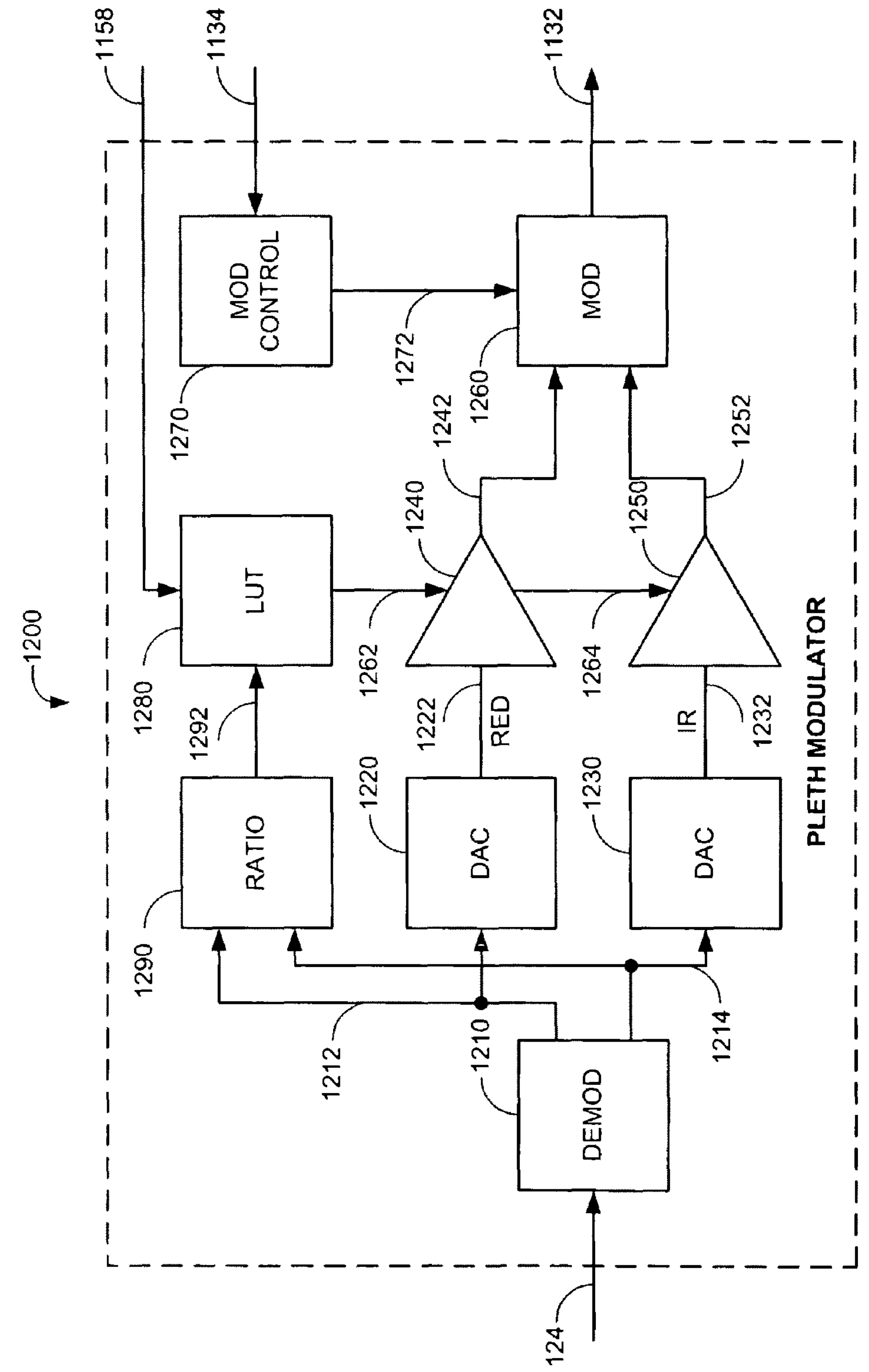
1158
1134
1132
MOD CONTROL
MOD
1272
1260
1270
1242
1252
LUT
1240
1250
1200
1280
1262
1264
PLETH MODULATOR
1292
1222
RED
IR
1232
RATIO
DAC
DAC
1220
1230
1290
1212
1210
1214
DEMOD
1124

FIG. 12

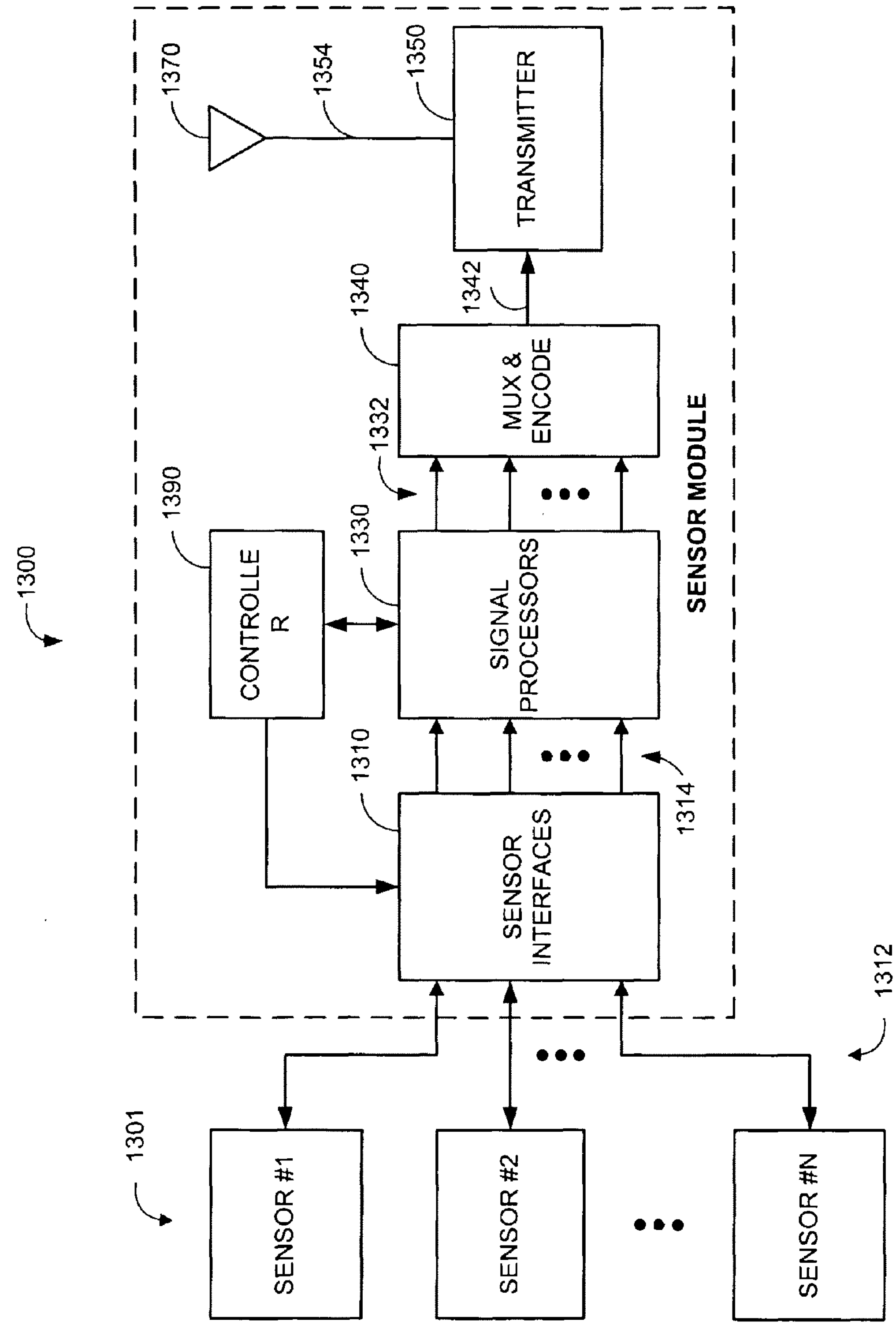
1300
SENSOR MODULE
TRANSMITTER
1350
1354
1370
MUX &
ENCODE
1340
1342
1332
CONTROLLE
R
1390
SIGNAL
PROCESSORS
1330
SENSOR
INTERFACES
1310
1314
SENSOR #1
SENSOR #2
SENSOR #N
1301
1312

FIG. 13

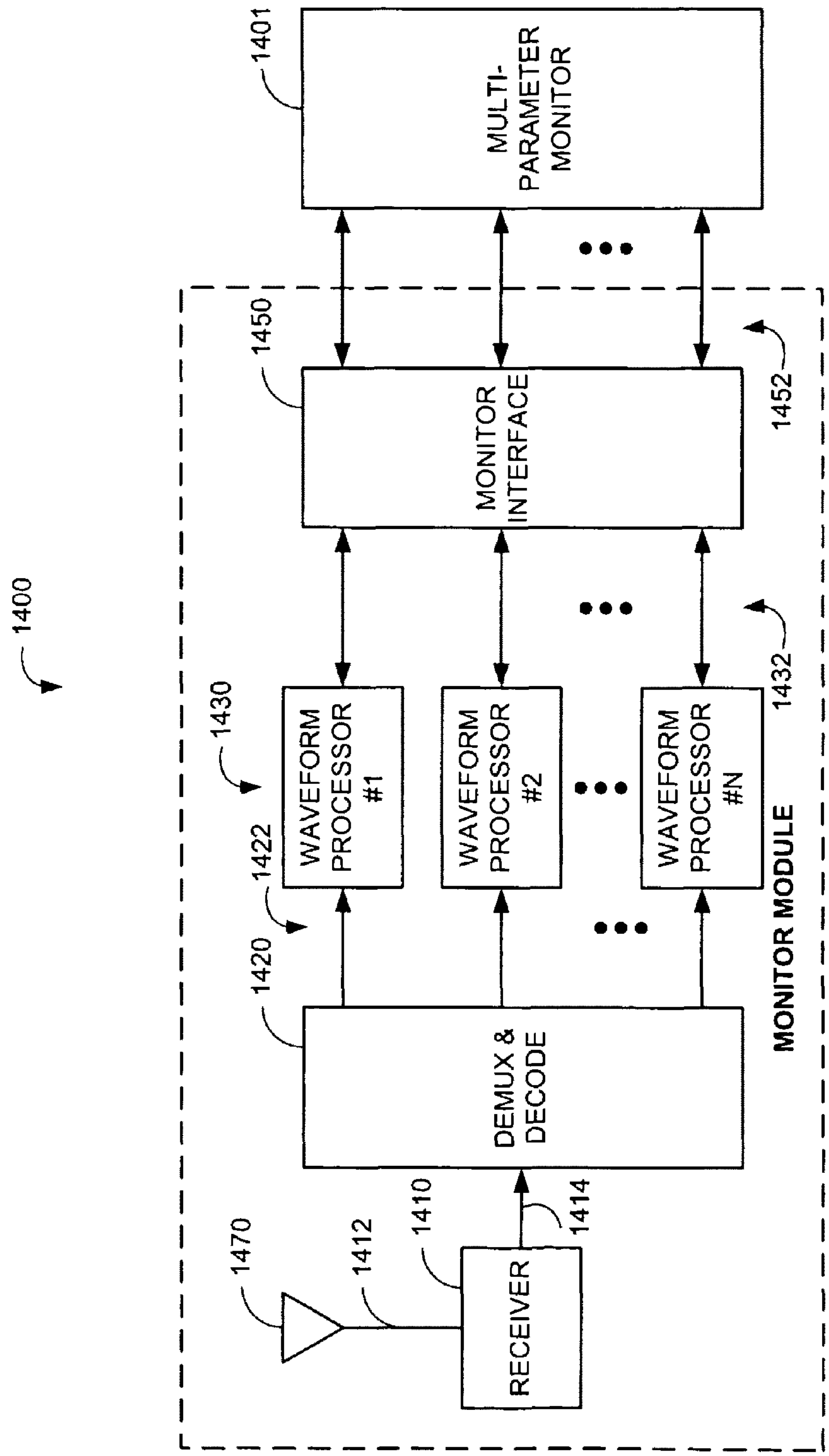
1400
1401
MULTI-PARAMETER MONITOR
1450
MONITOR INTERFACE
1452
1430
1432
WAVEFORM PROCESSOR #1
WAVEFORM PROCESSOR #2
WAVEFORM PROCESSOR #N
1422
1420
DEMUX & DECODE
MONITOR MODULE
1470
1412
1410
1414
RECEIVER

FIG. 14

ARM MOUNTABLE PORTABLE PATIENT MONITOR

REFERENCE TO RELATED APPLICATION

The present application is a continuation of U.S. patent application Ser. No. 15/448,989, filed on Mar. 3, 2017, entitled "Physiological Measurement Communications Adapter," which is a continuation of U.S. patent application Ser. No. 14/815,232, filed on Jul. 31, 2015, entitled "Physiological Measurement Communications Adapter," which is a continuation of U.S. patent application Ser. No. 14/217,788, filed on Mar. 18, 2014, entitled "Wrist-Mounted Physiological Measurement Device," now U.S. Pat. No. 9,113,832, which is a continuation of U.S. patent application Ser. No. 14/037,137, filed on Sep. 25, 2013, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 9,113,831, which is a continuation of U.S. patent application Ser. No. 12/955,826, filed on Nov. 29, 2010, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 8,548,548, which is a continuation of U.S. patent application Ser. No. 11/417,006, filed on May 3, 2006, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 7,844,315, which claims priority benefit under 35 U.S.C. §120 to, and is a continuation of, U.S. patent application Ser. No. 11/048,330, filed Feb. 1, 2005, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 7,844,314, which is a continuation of U.S. patent application Ser. No. 10/377,933, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 6,850,788, which claims priority benefit under 35 U.S.C. §119(e) from U.S. Provisional Application No. 60/367,428, filed Mar. 25, 2002, entitled "Physiological Measurement Communications Adapter." The present application also incorporates the foregoing utility disclosures herein by reference.

BACKGROUND OF THE INVENTION

Patient vital sign monitoring may include measurements of blood oxygen, blood pressure, respiratory gas, and EKG among other parameters. Each of these physiological parameters typically requires a sensor in contact with a patient and a cable connecting the sensor to a monitoring device. For example, FIGS. **1-2** illustrate a conventional pulse oximetry system **100** used for the measurement of blood oxygen. As shown in FIG. **1**, a pulse oximetry system has a sensor **110**, a patient cable **140** and a monitor **160**. The sensor **110** is typically attached to a finger **10** as shown. The sensor **110** has a plug **118** that inserts into a patient cable socket **142**. The monitor **160** has a socket **162** that accepts a patient cable plug **144**. The patient cable **140** transmits an LED drive signal **252** (FIG. **2**) from the monitor **160** to the sensor **110** and a resulting detector signal **254** (FIG. **2**) from the sensor **110** to the monitor **160**. The monitor **160** processes the detector signal **254** (FIG. **2**) to provide, typically, a numerical readout of the patient's oxygen saturation, a numerical readout of pulse rate, and an audible indicator or "beep" that occurs in response to each arterial pulse.

As shown in FIG. **2**, the sensor **110** has both red and infrared LED emitters **212** and a photodiode detector **214**. The monitor **160** has a sensor interface **271**, a signal processor **273**, a controller **275**, output drivers **276**, a display and audible indicator **278**, and a keypad **279**. The monitor **160** determines oxygen saturation by computing the differential absorption by arterial blood of the two wavelengths emitted by the sensor emitters **212**, as is well-known in the art. The sensor interface **271** provides LED drive current **252** which alternately activates the red and IR LED emitters **212**. The photodiode detector **214** generates a signal **254** corresponding to the red and infrared light energy attenuated from transmission through the patient finger **10** (FIG. **1**). The sensor interface **271** also has input circuitry for amplification, filtering and digitization of the detector signal **254**. The signal processor **273** calculates a ratio of detected red and infrared intensities, and an arterial oxygen saturation value is empirically determined based on that ratio. The controller **275** provides hardware and software interfaces for managing the display and audible indicator **278** and keypad **279**. The display and audible indicator **278** shows the computed oxygen status, as described above, and provides the pulse beep as well as alarms indicating oxygen desaturation events. The keypad **279** provides a user interface for setting alarm thresholds, alarm enablement, and display options, to name a few.

SUMMARY OF THE INVENTION

Conventional physiological measurement systems are limited by the patient cable connection between sensor and monitor. A patient must be located in the immediate vicinity of the monitor. Also, patient relocation requires either disconnection of monitoring equipment and a corresponding loss of measurements or an awkward simultaneous movement of patient equipment and cables. Various devices have been proposed or implemented to provide wireless communication links between sensors and monitors, freeing patients from the patient cable tether. These devices, however, are incapable of working with the large installed base of existing monitors and sensors, requiring caregivers and medical institutions to suffer expensive wireless upgrades. It is desirable, therefore, to provide a communications adapter that is plug-compatible both with existing sensors and monitors and that implements a wireless link replacement for the patient cable.

An aspect of a physiological measurement communications adapter comprises a sensor interface configured to receive a sensor signal. A transmitter modulates a first baseband signal responsive to the sensor signal so as to generate a transmit signal. A receiver demodulates a receive signal corresponding to the transmit signal so as to generate a second baseband signal corresponding to the first baseband signal. Further, a monitor interface is configured to communicate a waveform responsive to the second baseband signal to a sensor port of a monitor. The waveform is adapted to the monitor so that measurements derived by the monitor from the waveform are generally equivalent to measurements derivable from the sensor signal. The communications adapter may further comprise a signal processor having an input in communications with the sensor interface, where the signal processor is operable to derive a parameter responsive to the sensor signal and where the first baseband signal is responsive to the parameter. The parameter may correspond to at least one of a measured oxygen saturation and a pulse rate.

One embodiment may further comprise a waveform generator that synthesizes the waveform from a predetermined shape. The waveform generator synthesizes the waveform at a frequency adjusted to be generally equivalent to the pulse rate. The waveform may have a first amplitude and a second amplitude, and the waveform generator may be configured to adjusted the amplitudes so that measurements derived by the monitor are generally equivalent to a measured oxygen saturation.

In another embodiment, the sensor interface is operable on the sensor signal to provide a plethysmograph signal output, where the first baseband signal is responsive to the plethysmograph signal. This embodiment may further comprise a waveform modulator that modifies a decoded signal responsive to the second baseband signal to provide the waveform. The waveform modulator may comprise a demodulator that separates a first signal and a second signal from the decoded signal, an amplifier that adjusts amplitudes of the first and second signals to generate a first adjusted signal and a second adjusted signal, and a modulator that combines the first and second adjusted signals into the waveform. The amplitudes of the first and second signals may be responsive to predetermined calibration data for the sensor and the monitor.

An aspect of a physiological measurement communications adapter method comprises the steps of inputting a sensor signal at a patient location, communicating patient data derived from the sensor signal between the patient location and a monitor location, constructing a waveform at the monitor location responsive to the sensor signal, and providing the waveform to a monitor via a sensor port. The waveform is constructed so that the monitor calculates a parameter generally equivalent to a measurement derivable from the sensor signal.

In one embodiment, the communicating step may comprise the substeps of deriving a conditioned signal from the sensor signal, calculating a parameter signal from the conditioned signal, and transmitting the parameter signal from the patient location to the monitor location. The constructing step may comprise the substep of synthesizing the waveform from the parameter signal. In an alternative embodiment, the communicating step may comprise the substeps of deriving a conditioned signal from said sensor signal and transmitting the conditioned signal from the patient location to the monitor location. The constructing step may comprise the substeps of demodulating the conditioned signal and remodulating the conditioned signal to generate the waveform. The providing step may comprise the substeps of inputting a monitor signal from an LED drive output of the sensor port, modulating the waveform in response to the monitor signal, and outputting the waveform on a detector input of the sensor port.

Another aspect of a physiological measurement communications adapter comprises a sensor interface means for inputting a sensor signal and outputting a conditioned signal, a transmitter means for sending data responsive to the sensor signal, and a receiver means for receiving the data. The communications adapter further comprises a waveform processor means for constructing a waveform from the data so that measurements derived by a monitor from the waveform are generally equivalent to measurements derivable from the sensor signal, and a monitor interface means for communicating the waveform to a sensor port of the monitor. The communications adapter may further comprise a signal processor means for deriving a parameter signal from the conditioned signal, where the data comprises the parameter signal. The waveform processor means may comprise a means for synthesizing the waveform from the parameter signal. The data may comprise the conditioned signal, and the waveform processor means may comprise a means for modulating the conditioned signal in response to the monitor.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an illustration of a prior art pulse oximetry system;

FIG. **2** is a functional block diagram of a prior art pulse oximetry system;

FIG. **3** is an illustration of a physiological measurement communications adapter;

FIGS. **4**A-B are illustrations of communications adapter sensor modules;

FIGS. **5**A-C are illustrations of communications adapter monitor modules;

FIG. **6** is a functional block diagram of a communications adapter sensor module;

FIG. **7** is a functional block diagram of a communications adapter monitor module;

FIG. **8** is a functional block diagram of a sensor module configured to transmit measured pulse oximeter parameters;

FIG. **9** is a functional block diagram of a monitor module configured to received measured pulse oximeter parameters;

FIG. **10** is a functional block diagram of a sensor module configured to transmit a plethysmograph;

FIG. **11** is a functional block diagram of a monitor module configured to receive a plethysmograph;

FIG. **12** is a functional block diagram of a waveform modulator;

FIG. **13** is a functional block diagram of a sensor module configured for multiple sensors; and

FIG. **14** is a functional block diagram of a monitor module configured for multiple sensors.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Overview

FIG. **3** illustrates one embodiment of a communications adapter. FIGS. **4-5** illustrate physical configurations for a communications adapter. In particular, FIGS. **4**A-B illustrate sensor module configurations and FIGS. **5**A-C illustrate monitor module configurations. FIGS. **6-14** illustrate communications adapter functions. In particular, FIGS. **6-7** illustrate general functions for a sensor module and a monitor module, respectively. FIGS. **8-9** functionally illustrate a communications adapter where derived pulse oximetry parameters, such as saturation and pulse rate are transmitted between a sensor module and a monitor module. Also, FIGS. **10-12** functionally illustrate a communications adapter where a plethysmograph is transmitted between a sensor module and a monitor module. FIGS. **13-14** functionally illustrate a multiple-parameter communications adapter.

FIG. **3** illustrates a communications adapter **300** having a sensor module **400** and a monitor module **500**. The communications adapter **300** communicates patient data derived from a sensor **310** between the sensor module **400**, which is located proximate a patient **20** and the monitor module **500**, which is located proximate a monitor **360**. A wireless link **340** is provided between the sensor module **400** and the monitor module **500**, replacing the conventional patient cable, such as a pulse oximetry patient cable **140** (FIG. **1**). Advantageously, the sensor module **400** is plug-compatible with a conventional sensor **310**. In particular, the sensor connector **318** connects to the sensor module **400** in a similar manner as to a patient cable. Further, the sensor module **400** outputs a drive signal to the sensor **310** and inputs a sensor signal from the sensor **310** in an equivalent manner as a conventional monitor **360**. The sensor module **400** may be battery powered or externally powered. External power may be for recharging internal batteries or for powering the sensor module during operation or both.

As shown in FIG. **3**, the monitor module **500** is advantageously plug-compatible with a conventional monitor **360**. In particular, the monitor's sensor port **362** connects to the monitor module **500** in a similar manner as to a patient cable, such as a pulse oximetry patient cable **140** (FIG. **1**). Further, the monitor module **500** inputs a drive signal from the monitor **360** and outputs a corresponding sensor signal to the monitor **360** in an equivalent manner as a conventional sensor **310**. As such, the combination sensor module **400** and monitor module **500** provide a plug-compatible wireless replacement for a patient cable, adapting an existing wired physiological measurement system into a wireless physiological measurement system. The monitor module **500** may be battery powered, powered from the monitor, such as by tapping current from a monitor's LED drive, or externally powered from an independent AC or DC power source.

Although a communications adapter **300** is described herein with respect to a pulse oximetry sensor and monitor, one of ordinary skill in the art will recognize that a communications adapter may provide a plug-compatible wireless replace for a patient cable that connects any physiological sensor and corresponding monitor. For example, a communications adapter **300** may be applied to a biopotential sensor, a non-invasive blood pressure (NIBP) sensor, a respiratory rate sensor, a glucose sensor and the corresponding monitors, to name a few.

Sensor Module Physical Configurations

FIGS. **4**A-B illustrate physical embodiments of a sensor module **400**. FIG. **4**A illustrates a wrist-mounted module **410** having a wrist strap **411**, a case **412** and an auxiliary cable **420**. The case **412** contains the sensor module electronics, which are functionally described with respect to FIG. **6**, below. The case **412** is mounted to the wrist strap **411**, which attaches the wrist-mounted module **410** to a patient **20**. The auxiliary cable **420** mates to a sensor connector **318** and a module connector **414**, providing a wired link between a conventional sensor **310** and the wrist-mounted module **410**. Alternatively, the auxiliary cable **420** is directly wired to the sensor module **400**. The wrist-mounted module **410** may have a display **415** that shows sensor measurements, module status and other visual indicators, such as monitor status. The wrist-mounted module **410** may also have keys (not shown) or other input mechanisms to control its operational mode and characteristics. In an alternative embodiment, the sensor **310** may have a tail (not shown) that connects directly to the wrist-mounted module **410**, eliminating the auxiliary cable **420**.

FIG. **4**B illustrates a clip-on module **460** having a clip **461**, a case **462** and an auxiliary cable **470**. The clip **461** attaches the clip-on module **460** to patient clothing or objects near a patient **20**, such as a bed frame. The auxiliary cable **470** mates to the sensor connector **318** and functions as for the auxiliary cable **420** (FIG. **4**A) of the wrist-mounted module **410** (FIG. **4**A), described above. The clip-on module **460** may have a display **463** and keys **464** as for the wrist-mounted module **410** (FIG. **4**A). Either the wrist-mounted module **410** or the clip-on module **460** may have other input or output ports (not shown) that download software, configure the module, or provide a wired connection to other measurement instruments or computing devices, to name a few examples.

Monitor Module Physical Configurations

FIGS. **5**A-C illustrate physical embodiments of a monitor module **500**. FIG. **5**A illustrates a direct-connect module **510** having a case **512** and an integrated monitor connector **514**. The case **512** contains the monitor module electronics, which are functionally described with respect to FIG. **7**, below. The monitor connector **514** mimics that of the monitor end of a patient cable, such as a pulse oximetry patient cable **140** (FIG. **1**), and electrically and mechanically connects the monitor module **510** to the monitor **360** via the monitor's sensor port **362**.

FIG. **5**B illustrates a cable-connect module **540** having a case **542** and an auxiliary cable **550**. The case **542** functions as for the direct-connect module **510** (FIG. **5**A), described above. Instead of directly plugging into the monitor **360**, the cable-connect module **540** utilizes the auxiliary cable **550**, which mimics the monitor end of a patient cable, such as a pulse oximetry patient cable **140** (FIG. **1**), and electrically connects the cable-connect module **540** to the monitor sensor port **362**.

FIG. **5**C illustrates a plug-in module **570** having a plug-in case **572** and an auxiliary cable **580**. The plug-in case **572** is mechanically compatible with the plug-in chassis of a multiparameter monitor **370** and may or may not electrically connect to the chassis backplane. The auxiliary cable **580** mimics a patient cable and electrically connects the plug-in module **570** to the sensor port **372** of another plug-in device. A direct-connect module **510** (FIG. **5**A) or a cable-connect module **540** (FIG. **5**B) may also be used with a multiparameter monitor **370**.

In a multiparameter embodiment, such as described with respect to FIGS. **13**-**14**, below, a monitor module **500** may connect to multiple plug-in devices of a multiparameter monitor **370**. For example, a cable-connect module **540** (FIG. **5**B) may have multiple auxiliary cables **550** (FIG. **5**B) that connect to multiple plug-in devices installed within a multiparameter monitor chassis. Similarly, a plug-in module **570** may have one or more auxiliary cables **580** with multiple connectors for attaching to the sensor ports **372** of multiple plug-in devices.

Communications Adapter Functions

FIGS. **6**-**7** illustrate functional embodiments of a communications adapter. FIG. **6** illustrates a sensor module **400** having a sensor interface **610**, a signal processor **630**, an encoder **640**, a transmitter **650** and a transmitting antenna **670**. A physiological sensor **310** provides an input sensor signal **612** at the sensor connector **318**. Depending on the sensor **310**, the sensor module **400** may provide one or more drive signals **618** to the sensor **310**. The sensor interface **610** inputs the sensor signal **612** and outputs a conditioned signal **614**. The conditioned signal **614** may be coupled to the transmitter **650** or further processed by a signal processor **630**. If the sensor module configuration utilizes a signal processor **630**, it derives a parameter signal **632** responsive to the sensor signal **612**, which is then coupled to the transmitter **650**. Regardless, the transmitter **650** inputs a baseband signal **642** that is responsive to the sensor signal **612**. The transmitter **650** modulates the baseband signal **642** with a carrier to generate a transmit signal **654**. The transmit signal **654** may be derived by various amplitude, frequency or phase modulation schemes, as is well known in the art. The transmit signal **654** is coupled to the transmit antenna **670**, which provides wireless communications to a corresponding receive antenna **770** (FIG. **7**), as described below.

As shown in FIG. **6**, the sensor interface **610** conditions and digitizes the sensor signal **612** to generate the conditioned signal **614**. Sensor signal conditioning may be performed in the analog domain or digital domain or both and may include amplification and filtering in the analog domain and filtering, buffering and data rate modification in the digital domain, to name a few. The resulting conditioned signal **614** is responsive to the sensor signal **612** and may be used to calculate or derive a parameter signal **632**.

Further shown in FIG. **6**, the signal processor **630** performs signal processing on the conditioned signal **614** to generate the parameter signal **632**. The signal processing may include buffering, digital filtering, smoothing, averaging, adaptive filtering and frequency transforms to name a few. The resulting parameter signal **632** may be a measurement calculated or derived from the conditioned signal, such as oxygen saturation, pulse rate, blood glucose, blood pressure and EKG to name a few. Also, the parameter signal **632** may be an intermediate result from which the above-stated measurements may be calculated or derived.

As described above, the sensor interface **610** performs mixed analog and digital pre-processing of an analog sensor signal and provides a digital output signal to the signal processor **630**. The signal processor **630** then performs digital post-processing of the front-end processor output. In alternative embodiments, the input sensor signal **612** and the output conditioned signal **614** may be either analog or digital, the front-end processing may be purely analog or purely digital, and the back-end processing may be purely analog or mixed analog or digital.

In addition, FIG. **6** shows an encoder **640**, which translates a digital word or serial bit stream, for example, into the baseband signal **642**, as is well-known in the art. The baseband signal **642** comprises the symbol stream that drives the transmit signal **654** modulation, and may be a single signal or multiple related signal components, such as in-phase and quadrature signals. The encoder **640** may include data compression and redundancy, also well-known in the art.

FIG. **7** illustrates a monitor module **500** having a receive antenna **770**, a receiver **710**, a decoder **720**, a waveform processor **730** and a monitor interface **750**. A receive signal **712** is coupled from the receive antenna **770**, which provides wireless communications to a corresponding transmit antenna **670** (FIG. **6**), as described above. The receiver **710** inputs the receive signal **712**, which corresponds to the transmit signal **654** (FIG. **6**). The receiver **710** demodulates the receive signal to generate a baseband signal **714**. The decoder **720** translates the symbols of the demodulated baseband signal **714** into a decoded signal **724**, such as a digital word stream or bit stream. The waveform processor **730** inputs the decoded signal **724** and generates a constructed signal **732**. The monitor interface **750** is configured to communicate the constructed signal **732** to a sensor port **362** of a monitor **360**. The monitor **360** may output a sensor drive signal **754**, which the monitor interface **750** inputs to the waveform processor **730** as a monitor drive signal **734**. The waveform processor **730** may utilize the monitor drive signal **734** to generate the constructed signal **732**. The monitor interface **750** may also provide characterization information **758** to the waveform processor **730**, relating to the monitor **360**, the sensor **310** or both, that the waveform processor **730** utilizes to generate the constructed signal **732**.

The constructed signal **732** is adapted to the monitor **360** so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent to measurements derivable from the sensor signal **612** (FIG. **6**). Note that the sensor **310** (FIG. **6**) may or may not be directly compatible with the monitor **360**. If the sensor **310** (FIG. **6**) is compatible with the monitor **360**, the constructed signal **732** is generated so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent (within clinical significance) with those derivable directly from the sensor signal **612** (FIG. **6**). If the sensor **310** (FIG. **6**) is not compatible with the monitor **360**, the constructed signal **732** is generated so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent to those derivable directly from the sensor signal **612** (FIG. **6**) using a compatible monitor.

Wireless Pulse Oximetry

FIGS. **8-11** illustrate pulse oximeter embodiments of a communications adapter. FIGS. **8-9** illustrate a sensor module and a monitor module, respectively, configured to communicate measured pulse oximeter parameters. FIG. **10-11** illustrate a sensor module and a monitor module, respectively, configured to communicate a plethysmograph signal.

Parameter Transmission

FIG. **8** illustrates a pulse oximetry sensor module **800** having a sensor interface **810**, signal processor **830**, encoder **840**, transmitter **850**, transmitting antenna **870** and controller **890**. The sensor interface **810**, signal processor **830** and controller **890** function as described with respect to FIG. **2**, above. The sensor interface **810** communicates with a standard pulse oximetry sensor **310**, providing an LED drive signal **818** to the LED emitters **312** and receiving a sensor signal **812** from the detector **314** in response. The sensor interface **810** provides front-end processing of the sensor signal **812**, also described above, providing a plethysmograph signal **814** to the signal processor **830**. The signal processor **830** then derives a parameter signal **832** that comprises a real time measurement of oxygen saturation and pulse rate. The parameter signal **832** may include other parameters, such as measurements of perfusion index and signal quality. In one embodiment, the signal processor is an MS-5 or MS-7 board available from Masimo Corporation, Irvine, Calif.

As shown in FIG. **8**, the encoder **840**, the transmitter **850** and the transmitting antenna **870** function as described with respect to FIG. **6**, above. For example, the parameter signal **832** may be a digital word stream that is serialized into a bit stream and encoded into a baseband signal **842**. The baseband signal **842** may be, for example, two bit symbols that drive a quadrature phase shift keyed (QPSK) modulator in the transmitter **850**. Other encodings and modulations are also applicable, as described above. The transmitter **850** inputs the baseband signal **842** and generates a transmit signal **854** that is a modulated carrier having a frequency suitable for short-range transmission, such as within a hospital room, doctor's office, emergency vehicle or critical care ward, to name a few. The transmit signal **854** is coupled to the transmit antenna **870**, which provides wireless communications to a corresponding receive antenna **970** (FIG. **9**), as described below.

FIG. **9** illustrates a monitor module **900** having a receive antenna **970**, a receiver **910**, a decoder **920**, a waveform generator **930** and an interface cable **950**. The receive antenna **970**, receiver **910** and decoder **920** function as described with respect to FIG. **7**, above. In particular, the receive signal **912** is coupled from the receive antenna **970**, which provides wireless communications to a corresponding transmit antenna **870** (FIG. **8**). The receiver **910** inputs the receive signal **912**, which corresponds to the transmit signal **854** (FIG. **8**). The receiver **810** demodulates the receive signal **912** to generate a baseband signal **914**. Not accounting for transmission errors, the baseband signal **914** corresponds to the sensor module baseband signal **842** (FIG. **8**), for example a symbol stream of two bits each. The decoder **920** assembles the baseband signal **914** into a parameter signal **924**, which, for example, may be a sequence of digital words corresponding to oxygen saturation and pulse rate. Again, not accounting for transmission errors, the monitor

module parameter signal **924** corresponds to the sensor module parameter signal **832** (FIG. **8**), derived by the signal processor **830** (FIG. **8**).

Also shown in FIG. **9**, the waveform generator **930** is a particular embodiment of the waveform processor **730** (FIG. **7**) described above. The waveform generator **930** generates a synthesized waveform **932** that the pulse oximeter monitor **360** can process to calculate SpO_2 and pulse rate values or exception messages. In the present embodiment, the waveform generator output does not reflect a physiological waveform. In particular, the synthesized waveform is not physiological data from the sensor module **800**, but is a waveform synthesized from predetermined stored waveform data to cause the monitor **360** to calculate oxygen saturation and pulse rate equivalent to or generally equivalent (within clinical significance) to that calculated by the signal processor **830** (FIG. **8**). The actual intensity signal from the patient received by the detector **314** (FIG. **8**) is not provided to the monitor **360** in the present embodiment. Indeed, the waveform provided to the monitor **360** will usually not resemble a plethysmographic waveform or other physiological data from the patient to whom the sensor module **800** (FIG. **8**) is attached.

The synthesized waveform **932** is modulated according to the drive signal input **934**. That is, the pulse oximeter monitor **360** expects to receive a red and IR modulated intensity signal originating from a detector, as described with respect to FIGS. **1**-**2**, above. The waveform generator **930** generates the synthesized waveform **932** with a predetermined shape, such as a triangular or sawtooth waveform stored in waveform generator memory or derived by a waveform generator algorithm. The waveform is modulated synchronously with the drive input **934** with first and second amplitudes that are processed in the monitor **360** as red and IR portions of a sensor signal. The frequency and the first and second amplitudes are adjusted so that pulse rate and oxygen saturation measurements derived by the pulse oximeter monitor **360** are generally equivalent to the parameter measurements derived by the signal processor **830** (FIG. **8**), as described above. One embodiment of a waveform generator **930** is described in U.S. Patent Application No. 60/117,097 entitled "Universal/Upgrading Pulse Oximeter," assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein. Although the waveform generator **930** is described above as synthesizing a waveform that does not resemble a physiological signal, one of ordinary skill will recognize that another embodiment of the waveform generator **930** could incorporate, for example, a plethysmograph simulator or other physiological signal simulator.

Further shown in FIG. **9**, the interface cable **950** functions in a manner similar to the monitor interface **750** (FIG. **7**) described above. The interface cable **950** is configured to communicate the synthesized waveform **932** to the monitor **360** sensor port and to communicate the sensor drive signal **934** to the waveform generator **930**. The interface cable **950** may include a ROM **960** that contains monitor and sensor characterization data. The ROM **960** is read by the waveform generator **930** so that the synthesized waveform **932** is adapted to a particular monitor **360**. For example, the ROM **960** may contain calibration data of red/IR versus oxygen saturation, waveform amplitude and waveform shape information. An interface cable is described in U.S. Patent Application No. 60/117,092, referenced above. Monitor-specific SatShare™ brand interface cables are available from Masimo Corporation, Irvine, Calif. In an alternative embodiment, such as a direct connect monitor module as illustrated in FIG. **5**A, an interface cable **950** is not used and the ROM **960** may be incorporated within the monitor module **900** itself.

Plethysmograph Transmission

FIG. **10** illustrates another pulse oximetry sensor module **1000** having a sensor interface **1010**, encoder **1040**, transmitter **1050**, transmitting antenna **1070** and controller **1090**, which have the corresponding functions as those described with respect to FIG. **8**, above. The encoder **1040**, however, inputs a plethysmograph signal **1014** rather than oxygen saturation and pulse rate measurements **832** (FIG. **8**). Thus, the sensor module **1000** according to this embodiment encodes and transmits a plethysmograph signal **1014** to a corresponding monitor module **1100** (FIG. **11**) in contrast to derived physiological parameters, such as oxygen saturation and pulse rate. The plethysmograph signal **1014** is illustrated in FIG. **10** as being a direct output from the sensor interface **1010**. In another embodiment, the sensor module **1000** incorporates a decimation processor, not shown, after the sensor interface **1010** so as to provide a plethysmograph signal **1014** having a reduced sample rate.

FIG. **11** illustrates another pulse oximetry monitor module **1100** having a receive antenna **1170**, a receiver **1110**, a decoder **1120** and an interface cable **1150**, which have the corresponding functions as those described with respect to FIG. **9**, above. This monitor module embodiment **1100**, however, has a waveform modulator **1200** rather than a waveform generator **930** (FIG. **9**), as described above. The waveform modulator **1200** inputs a plethysmograph signal from the decoder **1120** rather than oxygen saturation and pulse rate measurements, as described with respect to FIG. **9**, above. Further, the waveform modulator **1200** provides an modulated waveform **1132** to the pulse oximeter monitor **360** rather than a synthesized waveform, as described with respect to FIG. **9**. The modulated waveform **1132** is a plethysmographic waveform modulated according to the monitor drive signal input **1134**. That is, the waveform modulator **1200** does not synthesize a waveform, but rather modifies the received plethysmograph signal **1124** to cause the monitor **360** to calculate oxygen saturation and pulse rate generally equivalent (within clinical significance) to that derivable by a compatible, calibrated pulse oximeter directly from the sensor signal **1012** (FIG. **10**). The waveform modulator **1200** is described in further detail with respect to FIG. **12**, below.

FIG. **12** shows a waveform modulator **1200** having a demodulator **1210**, a red digital-to-analog converter (DAC) **1220**, an IR DAC **1230**, a red amplifier **1240**, an IR amplifier **1250**, a modulator **1260**, a modulator control **1270**, a look-up table (LUT) **1280** and a ratio calculator **1290**. The waveform modulator **1200** demodulates red and IR plethysmographs ("pleths") from the decoder output **1124** into a separate red pleth **1222** and IR pleth **1232**. The waveform modulator **1200** also adjusts the amplitudes of the pleths **1222**, **1232** according to stored calibration curves for the sensor **310** (FIG. **10**) and the monitor **360** (FIG. **11**). Further, the waveform modulator **1200** re-modulates the adjusted red pleth **1242** and adjusted IR pleth **1252**, generating a modulated waveform **1132** to the monitor **360** (FIG. **11**).

As shown in FIG. **12**, the demodulator **1210** performs the demodulation function described above, generating digital red and IR pleth signals **1212**, **1214**. The DACs **1220**, **1230** convert the digital pleth signals **1212**, **1214** to corresponding analog pleth signals **1222**, **1232**. The amplifiers **1240**, **1250** have variable gain control inputs **1262**, **1264** and perform the amplitude adjustment function described above, generating adjusted red and IR pleth signals **1242**, **1252**. The

modulator **1260** performs the re-modulation function described above, combining the adjusted red and IR pleth signals **1242**, **1252** according to a control signal **1272**. The modulator control **1270** generates the control signal **1272** synchronously with the LED drive signal(s) **1134** from the monitor **360**.

Also shown in FIG. **12**, the ratio calculator **1290** derives a red/IR ratio from the demodulator outputs **1212**, **1214**. The LUT **1280** stores empirical calibration data for the sensor **310** (FIG. **10**). The LUT **1280** also downloads monitor-specific calibration data from the ROM **1160** (FIG. **11**) via the ROM output **1158**. From this calibration data, the LUT **1280** determines a desired red/IR ratio for the modulated waveform **1132** and generates red and IR gain outputs **1262**, **1264** to the corresponding amplifiers **1240**, **1250**, accordingly. A desired red/IR ratio is one that allows the monitor **360** (FIG. **11**) to derive oxygen saturation measurements from the modulated waveform **1132** that are generally equivalent to that derivable directly from the sensor signal **1012** (FIG. **10**).

One of ordinary skill in the art will recognize that some of the signal processing functions described with respect to FIGS. **8-11** may be performed either within a sensor module or within a monitor module. Signal processing functions performed within a sensor module may advantageously reduce the transmission bandwidth to a monitor module at a cost of increased sensor module size and power consumption. Likewise, signal processing functions performed within a monitor module may reduce sensor module size and power consumption at a cost of increase transmission bandwidth.

For example, a monitor module embodiment **900** (FIG. **9**) described above receives measured pulse oximeter parameters, such as oxygen saturation and pulse rate, and generates a corresponding synthesized waveform. In that embodiment, the oxygen saturation and pulse rate computations are performed within a sensor module **800** (FIG. **8**). Another monitor module embodiment **1100** (FIG. **11**), also described above, receives a plethysmograph waveform and generates a remodulated waveform. In that embodiment, minimal signal processing is performed within a sensor module **1000** (FIG. **10**). In yet another embodiment, not shown, a sensor module transmits a plethysmograph waveform or a decimated plethysmograph waveform having a reduced sample rate. A corresponding monitor module has a signal processor, such as described with respect to FIG. **8**, in addition to a waveform generator, as described with respect to FIG. **9**. The signal processor computes pulse oximeter parameters and the waveform generator generates a corresponding synthesized waveform, as described above. In this embodiment, minimal signal processing is performed within the sensor module, and the monitor module functions are performed on the pulse oximeter parameters computed within the monitor module.

Wireless Multiple Parameter Measurements

FIGS. **13-14** illustrate a multiple parameter communications adapter. FIG. **13** illustrates a multiple parameter sensor module **1300** having sensor interfaces **1310**, one or more signal processors **1330**, a multiplexer and encoder **1340**, a transmitter **1350**, a transmitting antenna **1370** and a controller **1390**. One or more physiological sensors **1301** provide input sensor signals **1312** to the sensor module **1300**. Depending on the particular sensors **1301**, the sensor module **1300** may provide one or more drive signals **1312** to the sensors **1301** as determined by the controller **1390**. The sensor interfaces **1310** input the sensor signals **1312** and output one or more conditioned signals **1314**. The conditioned signals **1314** may be coupled to the transmitter **1350** or further processed by the signal processors **1330**. If the sensor module configuration utilizes signal processors **1330**, it derives multiple parameter signals **1332** responsive to the sensor signals **1312**, which are then coupled to the transmitter **1350**. Regardless, the transmitter **1350** inputs a baseband signal **1342** that is responsive to the sensor signals **1312**. The transmitter **1350** modulates the baseband signal **1342** with a carrier to generate a transmit signal **1354**, which is coupled to the transmit antenna **1370** and communicated to a corresponding receive antenna **1470** (FIG. **14**), as described with respect to FIG. **6**, above. Alternatively, there may be multiple baseband signals **1342**, and the transmitter **1350** may transmit on multiple frequency channels, where each channel coveys data responsive to one or more of the sensor signals **1314**.

As shown in FIG. **13**, the sensor interface **1310** conditions and digitizes the sensor signals **1312** as described for a single sensor with respect to FIG. **6**, above. The resulting conditioned signals **1314** are responsive to the sensor signals **1312**. The signal processors **1330** perform signal processing on the conditioned signals **1314** to derive parameter signals **1332**, as described for a single conditioned signal with respect to FIG. **6**, above. The parameter signals **1332** may be physiological measurements such as oxygen saturation, pulse rate, blood glucose, blood pressure, EKG, respiration rate and body temperature to name a few, or may be intermediate results from which the above-stated measurements may be calculated or derived. The multiplexer and encoder **1340** combines multiple digital word or serial bit streams into a single digital word or bit stream. The multiplexer and encoder also encodes the digital word or bit stream to generate the baseband signal **1342**, as described with respect to FIG. **6**, above.

FIG. **14** illustrates a multiple parameter monitor module **1400** having a receive antenna **1470**, a receiver **1410**, a demultiplexer and decoder **1420**, one or more waveform processors **1430** and a monitor interface **1450**. The receiver **1410** inputs and demodulates the receive signal **1412** corresponding to the transmit signal **1354** (FIG. **13**) to generate a baseband signal **1414** as described with respect to FIG. **7**, above. The demultiplexer and decoder **1420** separates the symbol streams corresponding to the multiple conditioned signals **1314** (FIG. **13**) and/or parameter signals **1332** (FIG. **13**) and translates these symbol streams into multiple decoded signals **1422**, as described for a single symbol stream with respect to FIG. **7**, above. Alternatively, multiple frequency channels are received to generate multiple baseband signals, each of which are decoded to yield multiple decoded signals **1422**. The waveform processors **1430** input the decoded signals **1422** and generate multiple constructed signals **1432**, as described for a single decoded signal with respect to FIGS. **7-12**, above. The monitor interface **1450** is configured to communicate the constructed signals **1432** to the sensor ports of a multiple parameter monitor **1401** or multiple single parameter monitors, in a manner similar to that for a single constructed signal, as described with respect to FIGS. **7-12**, above. In particular, the constructed signals **1432** are adapted to the monitor **1401** so that measurements derived by the monitor **1401** from the constructed signals **1432** are generally equivalent to measurements derivable directly from the sensor signals **1312** (FIG. **13**).

A physiological measurement communications adapter is described above with respect to wireless communications and, in particular, radio frequency communications. A sensor module and monitor module, however, may also communicate via wired communications, such as telephone, Internet

or fiberoptic cable to name a few. Further, wireless communications can also utilize light frequencies, such as IR or laser to name a few.

A physiological measurement communications adapter has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only. One of ordinary skill in the art will appreciate many variations and modifications of a physiological measurement communications adapter within the scope of the claims that follow.

What is claimed is:

1. An arm mountable portable patient monitoring device configured for both on-patient monitoring of parameter measurements using one or more sensors operatively connected to the portable patient monitoring device and wireless transmission of parameter measurements, the portable patient monitoring device comprising:

a pulse oximetry sensor configured to be wrapped around a digit of a patient, the pulse oximetry sensor including at least:

a light emitter configured to emit light into a tissue site of the digit of the patient;

a light detector configured output a signal responsive to at least a portion of the emitted light after attenuation by tissue of the tissue site; and

a tail configured to electrically convey the signal;

a housing configured for, and having a size and shape configured for, mounting to a lower arm of the patient, the housing including at least:

a display positioned on a front side of the housing that is opposite a back side of the housing, the display configured to show a status of the portable patient monitoring device and one or more parameter measurements so as to be viewable by a user;

a first sensor port positioned on a first side of the housing, the first side of the housing configured to face toward a hand having the digit of the patient under measurement, the first sensor port configured to physically couple to the tail of the pulse oximetry sensor and to electrically receive the signal from the pulse oximetry sensor, wherein the first sensor port is positioned on the first side of the housing such that, when the tail is physically coupled to the first sensor port, the tail extends from the first sensor port along an axis perpendicular to a face of the first side of the housing on which the first sensor port is positioned;

a second sensor port configured to receive information from an EKG sensor arrangement via a wired connection;

a third sensor port configured to receive information from a blood pressure sensor arrangement via a wired connection;

a rechargeable battery configured to power the portable patient monitoring device including the pulse oximetry sensor;

one or more signal processing arrangements configured to:

receive the signal from the pulse oximetry sensor;

derive, based on the signal, measurements of oxygen saturation and pulse rate; and

cause to be displayed, on the display, the measurements of oxygen saturation and pulse rate; and

a transmitter configured to:

wirelessly transmit a transmit signal indicative of the measurements of oxygen saturation and pulse rate to a separate computing device configured to display the measurements of oxygen saturation and pulse rate; and

a strap mountable to the back side of the housing, the strap configured to secure the housing to the lower arm of the patient.

2. The portable patient monitoring device of claim 1, wherein the tail comprises a cable extending from the pulse oximetry sensor to the first sensor port of the housing.

3. The portable patient monitoring device of claim 2, wherein the cable is removably coupled to the first sensor port of the housing, and wherein the digit of the patient is a thumb of the patient.

4. The portable patient monitoring device of claim 1, wherein the one or more signal processing arrangements comprise at least:

a sensor interface configured to:

receive the signal from the pulse oximetry sensor; and

process the signal to generate a conditioned signal by at least one of:

amplification, filtering, analog to digital conversion, buffering, data rate modification, digital filtering, adaptive filtering, smoothing, averaging, or frequency transforming; and

a signal processor configured to:

receive the conditioned signal from the sensor interface;

derive, from the conditioned signal, the measurements of oxygen saturation and pulse rate; and

provide information indicative of the measurements of oxygen saturation and pulse rate to the transmitter.

5. The portable patient monitoring device of claim 4, wherein the sensor interface is further configured to:

provide the conditioned signal to the transmitter.

6. The portable patient monitoring device of claim 1 further comprising:

an EKG sensor arrangement in electrical communication with the second sensor port of the housing;

wherein the one or more signal processing arrangements are further configured to:

receive the information from the EKG sensor arrangement at least in part via digital communication;

determine, from the information from the EKG sensor arrangement, an EKG measurement; and

cause to be displayed, on the display, the EKG measurement;

wherein the housing further includes a data combining arrangement configured to:

combine at least information indicative of the measurements of oxygen saturation, pulse rate, and EKG; and

wherein the transmitter is further configured to:

wirelessly transmit the transmit signal indicative of the measurements of oxygen saturation, pulse rate, and EKG to the separate computing device configured to display the measurements of oxygen saturation, pulse rate, and EKG.

7. The portable patient monitoring device of claim 6 further comprising:

a blood pressure sensor arrangement in electrical communication with the third sensor port of the housing;

wherein the one or more signal processing arrangements are further configured to:

receive the information from the blood pressure sensor arrangement at least in part via digital communication;

determine, from the information from the blood pressure sensor arrangement, a measurement of blood pressure; and

cause to be displayed, on the display, the measurement of blood pressure;

wherein the data combining arrangement is further configured to:

combine at least information indicative of the measurements of oxygen saturation, pulse rate, EKG, and blood pressure; and

wherein the transmitter is further configured to:

wirelessly transmit the transmit signal indicative of the measurements of oxygen saturation, pulse rate, EKG, and blood pressure to the separate computing device configured to display the measurements of oxygen saturation, pulse rate, EKG, and blood pressure.

8. The portable patient monitoring device of claim **7**, wherein the one or more signal processing arrangements are further configured to:

cause the measurements of oxygen saturation, pulse rate, EKG, and blood pressure to all be displayed on the display of the portable patient monitoring device.

9. The portable patient monitoring device of claim **7**, wherein:

the one or more signal processing arrangements are further configured to:

receive the additional signals indicative of additional physiological parameters including at least one of: respiration rate or body temperature;

determine, from the additional signals, measurements of the additional physiological parameters; and

cause to be displayed, on the display, the measurements of the additional physiological parameters;

wherein the data combining arrangement is further configured to:

combine at least information indicative of the measurements of oxygen saturation, pulse rate, EKG, blood pressure and the additional physiological parameters; and

wherein the transmitter is further configured to:

wirelessly transmit the transmit signal indicative of the measurements of oxygen saturation, pulse rate, EKG, blood pressure, and additional physiological parameters to the separate computing device configured to display the measurements of oxygen saturation, pulse rate, EKG, blood pressure, and additional physiological parameters.

10. The portable patient monitoring device of claim **9**, wherein the one or more signal processing arrangements are further configured to:

cause the measurements of oxygen saturation, pulse rate, EKG, blood pressure, and additional physiological parameters to all be displayed on the display of the portable patient monitoring device.

11. The portable patient monitoring device of claim **10**, wherein the data combining arrangement is at least one of a multiplexer or an encoder.

12. The portable patient monitoring device of claim **1**, wherein the measurements of oxygen saturation and pulse rate comprise real time measurements of oxygen saturation and pulse rate.

13. The portable patient monitoring device of claim **1**, wherein the one or more signal processing arrangements are further configured to determine, based on the signal, a measurement of signal quality.

14. The portable patient monitoring device of claim **1**, wherein the housing further includes at least one or more user input mechanisms configured to control an operational mode of the portable patient monitoring device in response to inputs from a user.

15. The portable patient monitoring device of claim **1**, wherein the transmit signal indicative of the measurements of oxygen saturation and pulse rate comprises the derived measurements of oxygen saturation and pulse rate.

16. The portable patient monitoring device of claim **15**, wherein the transmit signal indicative of the measurements of oxygen saturation and pulse rate further comprises raw data indicative of the signal from the pulse oximetry sensor.

17. An arm mountable portable patient monitoring device configured for both on-patient monitoring of parameter measurements using one or more sensors operatively connected to the portable patient monitoring device and wireless transmission of parameter measurements, the portable patient monitoring device comprising:

a pulse oximetry sensor configured to be wrapped around a digit of a patient, the pulse oximetry sensor including at least:

a light emitter configured to emit light into a tissue site of the digit of the patient; and

a light detector configured output a signal responsive to at least a portion of the emitted light after attenuation by tissue of the tissue site;

a housing configured to be mounted to an arm of the patient, the housing including at least:

a display positioned on a front side of the housing that is opposite a back side of the housing, the display configured to show a status of the portable patient monitoring device and one or more parameter measurements so as to be viewable by a user;

a first sensor port positioned on a first side of the housing, the first side of the housing having a face that is configured to face toward a hand having the digit of the patient under measurement, the first sensor port configured to electrically receive the signal from the pulse oximetry sensor via a wire extending from the pulse oximetry sensor to the first sensor port, wherein the wire extends from the first sensor port perpendicularly to the face of the first side of the housing;

second and third sensor ports configured to receive signals from two or more additional sensor arrangements via wired communications;

a rechargeable battery configured to power the portable patient monitoring device including the pulse oximetry sensor;

one or more signal processing arrangements configured to:

receive the signal from the pulse oximetry sensor; and

cause to be displayed, on the display, measurements of oxygen saturation and pulse rate derived from the received signal; and

a transmitter configured to:

wirelessly transmit a transmit signal indicative of the measurements of oxygen saturation and pulse rate to a separate computing device configured to display the measurements of oxygen saturation and pulse rate; and

a strap mountable to the back side of the housing, the strap configured to secure the housing to the arm of the patient.

18. The portable patient monitoring device of claim **17** further comprising:

a second physiological sensor arrangement in electrical communication with the second sensor port of the housing, the second physiological sensor arrangement comprising at least one of: a blood pressure sensor arrangement, an EKG sensor arrangement, a respiration rate sensor arrangement, or a body temperature sensor arrangement;

wherein the one or more signal processing arrangements are further configured to:

receive information from the second physiological sensor arrangement indicative of a physiological parameter of the patient, wherein the information from the second physiological sensor arrangement is at least partly digital; and

cause to be displayed, on the display one or more additional parameter measurements, based on the information from the second physiological sensor arrangement, including measurements of at least one of: blood pressure, EKG, respiration rate, or body temperature;

wherein the transmitter is further configured to wirelessly transmit the transmit signal indicative of the measurements of oxygen saturation and pulse rate, and the one or more additional parameter measurements, to the separate computing device configured to display the measurements of oxygen saturation and pulse rate, and the one or more additional parameter measurements.

19. The portable patient monitoring device of claim **18** further comprising:

a third physiological sensor arrangement, different from the second physiological sensor arrangement, in electrical communication with the third sensor port of the housing, the third physiological sensor arrangement comprising at least one of: a blood pressure sensor arrangement, an EKG sensor arrangement, a respiration rate sensor arrangement, or a body temperature sensor arrangement;

wherein the one or more signal processing arrangements are further configured to:

receive information from the third physiological sensor arrangement indicative of a physiological parameter of the patient; and

cause to be displayed, on the display, the second one or more additional parameter measurements, based on information from the third physiological sensor arrangement, including measurements of at least one of: blood pressure, EKG, respiration rate, or body temperature;

wherein the transmitter is further configured to wirelessly transmit the transmit signal indicative of the measurements of oxygen saturation and pulse rate, the one or more additional parameter measurements, and the second one or more additional parameter measurements, to the separate computing device configured to display the measurements of oxygen saturation and pulse rate, the one or more additional parameter measurements, and the second one or more additional parameter measurements.

20. An arm mountable portable patient monitoring device configured for both on-patient monitoring of parameter measurements using one or more sensors operatively connected to the portable patient monitoring device and wireless transmission of parameter measurements, the portable patient monitoring device comprising:

a pulse oximetry sensor configured to be wrapped around a digit of a patient, the pulse oximetry sensor including at least:

a light emitter configured to emit light into a tissue site of the digit of the patient;

a light detector configured output a first signal responsive to at least a portion of the emitted light after attenuation by tissue of the tissue site; and

a cable extending from the pulse oximetry sensor and configured to electrically convey the first signal;

a blood pressure sensor configured to output a second signal responsive to at least a blood pressure parameter of the patient;

an additional sensor arrangement configured to output a third signal responsive to at least one additional physiological parameter of a patient other than blood pressure or oxygen saturation, the at least one additional physiological parameter including at least one of: temperature or respiration rate;

a housing configured to be secured to a lower arm of the patient, the housing having a size and shape configured to be secured to the lower arm of the patient;

a strap mountable to the back side of the housing, the strap configured to secure the housing to the lower arm of the patient;

a display positioned on a front side of the housing that is opposite a back side of the housing, the display configured to show a status of the portable patient monitoring device and one or more parameter measurements so as to be viewable by a user, wherein the display is positioned centrally on the front side of the display and is sized such that the display spans most of a length of a shortest dimension of the front side of the housing, and wherein the front side of the housing comprises a single user interface and a bezel;

one or more user input mechanisms configured to control an operational mode of the portable patient monitoring device in response to inputs from a user;

a first sensor port positioned on a first side of the housing, wherein:

the first side of the housing is configured to face toward a hand having the digit of the patient under measurement when the housing is secured to the lower arm of the patient,

the first sensor port is configured to removably physically couple with the pulse oximetry sensor via the cable and to electrically receive the first signal from the pulse oximetry sensor,

the cable is configured to run from the first sensor port, at least part way down the arm of the patient, and to the digit of the patient to which the pulse oximetry sensor is configured to be wrapped around,

the first sensor port is positioned on the first side of the housing such that, when the cable is physically coupled to the first sensor port, the cable extends from the first sensor port along a path perpendicular to the first side of the housing on which the first sensor port is positioned,

the front side of the housing is raised from the strap and the lower arm of the patient to enable positioning of the first sensor port on the first side of the housing between the lower arm of the patient and the front side of the housing, and

a top of the first sensor port is located below the front of the housing;

a second sensor port positioned on the housing and configured to provide electrical communication with the blood pressure sensor arrangement and to electrically receive second signal from the blood pressure sensor arrangement, wherein the second sensor port is

connectable to wire extending from the blood pressure sensor arrangement to provide the electrical communication with the blood pressure sensor arrangement;

a third sensor port positioned on the housing and configured to provide electrical communication with the additional sensor arrangement and to electrically receive the third signal from the additional sensor arrangement, wherein the third sensor port is connectable to wire extending from the additional sensor arrangement to provide the electrical communication with the additional sensor arrangement;

a rechargeable battery within the housing and configured to power the portable patient monitoring device including at least the pulse oximetry sensor such that the portable patient monitoring device is portable and wearable by the patient;

one or more signal processing arrangements within the housing and configured to:

receive the first signal from the pulse oximetry sensor via one or more sensor interfaces;

process the first signal from the pulse oximetry sensor to determine measurements of oxygen saturation and pulse rate, wherein the first signal is processed at least in part in the analog domain by at least one of: the one or more sensor interfaces, or the one or more signal processing arrangements;

receive the second signal from the blood pressure sensor arrangement via the one or more sensor interfaces, wherein the second signal is processed at least in part in the digital domain by at least one of: the one or more sensor interfaces, or the one or more signal processing arrangements;

receive the third signal from the additional sensor arrangement via the one or more sensor interfaces, wherein the third signal is processed at least in part in the digital domain by at least one of: the one or more sensor interfaces, or the one or more signal processing arrangements; and

cause the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter to all be displayed on the display of the portable patient monitoring device;

a multiplexer within the housing and configured to combine at least information indicative of the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter into a single digital word or bit stream;

an encoder within the housing and configured to encode the single digital word or bit stream to generate a baseband signal; and

a transmitter within the housing and configured to:

modulate the baseband signal with a carrier to generate a transmit signal; and

wirelessly transmit a transmit signal including the information indicating the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter to a separate computing device configured to decode the transmit signal and display, on a remote display, the measurements of oxygen saturation, pulse rate, blood pressure, and the at least one additional physiological parameter.

* * * * *

UNITED STATES PATENT AND TRADEMARK OFFICE

CERTIFICATE OF CORRECTION

PATENT NO. : 9,872,623 B2
APPLICATION NO. : 15/494967
DATED : January 23, 2018
INVENTOR(S) : Ammar Al-Ali

It is certified that error appears in the above-identified patent and that said Letters Patent is hereby corrected as shown below:

In Column 2 (page 11, item (56)) at Line 34, Under Other Publications, change "Aitkonhead" to --Aitkenhead--.

In Column 8 at Line 8, Change "FIG." to --FIGS.--.

In Column 13 at Line 25, In Claim 1, after "configured" insert --to--.

In Column 16 at Line 24 (approx.), In Claim 17, after "configured" insert --to--.

In Column 18 at Line 3, In Claim 20, after "configured" insert --to--.

Signed and Sealed this
Twenty-ninth Day of May, 2018

Andrei Iancu
Director of the United States Patent and Trademark Office

US00RE47218E

(19) **United States**
(12) **Reissued Patent**
Al-Ali

(10) **Patent Number: US RE47,218 E**
(45) **Date of Reissued Patent: Feb. 5, 2019**

(54) **ADAPTIVE ALARM SYSTEM**

(71) Applicant: **MASIMO Corporation**, Irvine, CA (US)

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(21) Appl. No.: **15/881,602**

(22) Filed: **Jan. 26, 2018**

Related U.S. Patent Documents

Reissue of:

(64) Patent No.: **9,775,570**
Issued: **Oct. 3, 2017**
Appl. No.: **15/583,718**
Filed: **May 1, 2017**

U.S. Applications:

(63) Continuation of application No. 13/037,184, filed on Feb. 28, 2011, now Pat. No. 9,724,024.

(60) Provisional application No. 61/328,630, filed on Apr. 27, 2010, provisional application No. 61/309,419, filed on Mar. 1, 2010.

(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 5/1455 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 5/746*** (2013.01); *A61B 5/1455* (2013.01); *A61B 5/14552* (2013.01)

(58) **Field of Classification Search**
CPC ... A61B 5/746; A61B 5/1455; A61B 5/14552; A61B 5/74
USPC 600/300, 301, 310, 322, 323, 324, 473, 600/476, 500, 508; 356/41, 573.1
See application file for complete search history.

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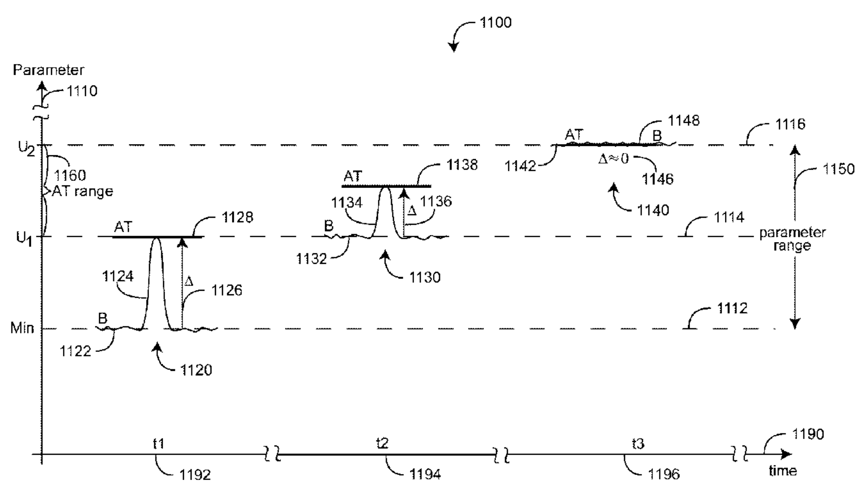
(57) **ABSTRACT**

Systems and electronic processes for reducing electronic alarms in a medical patient monitoring system. For example, a system for reducing electronic alarms can include an optical sensor and one or more hardware processors in electronic communication with the optical sensor. The one or more hardware processors can be programmed to measure oxygen saturation values of a patient over a first period of time, determine if at least one oxygen saturation value obtained over the first period of time exceeds a first alarm threshold, determine whether a first alarm should be triggered based on the determination that the at least one oxygen saturation value obtained over the first period of time exceeds the first alarm threshold, determine a second alarm threshold to be applied during a second period of time subsequent to the first period of time, the second alarm threshold replacing the first alarm threshold.

17 Claims, 14 Drawing Sheets



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2014/0323898	A1	10/2014	Purdon et al.
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2015/0097701	A1	4/2015	Al-Ali et al.
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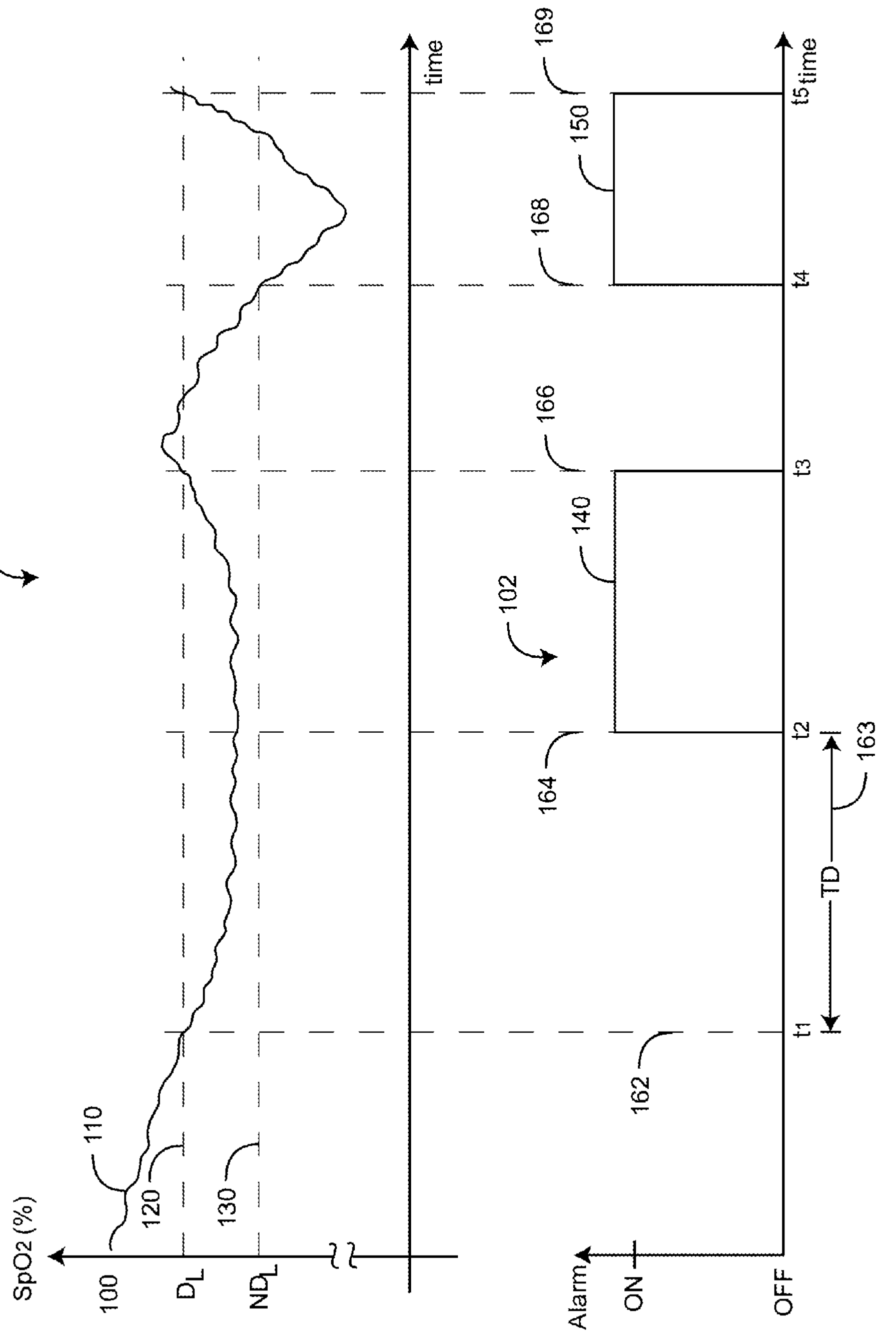
100
SpO2 (%)
100
D_L
ND_L
110
120
130
time
102
Alarm
ON
OFF
162
164
166
168
169
140
150
163
TD
t1
t2
t3
t4
t5
time

FIG. 1

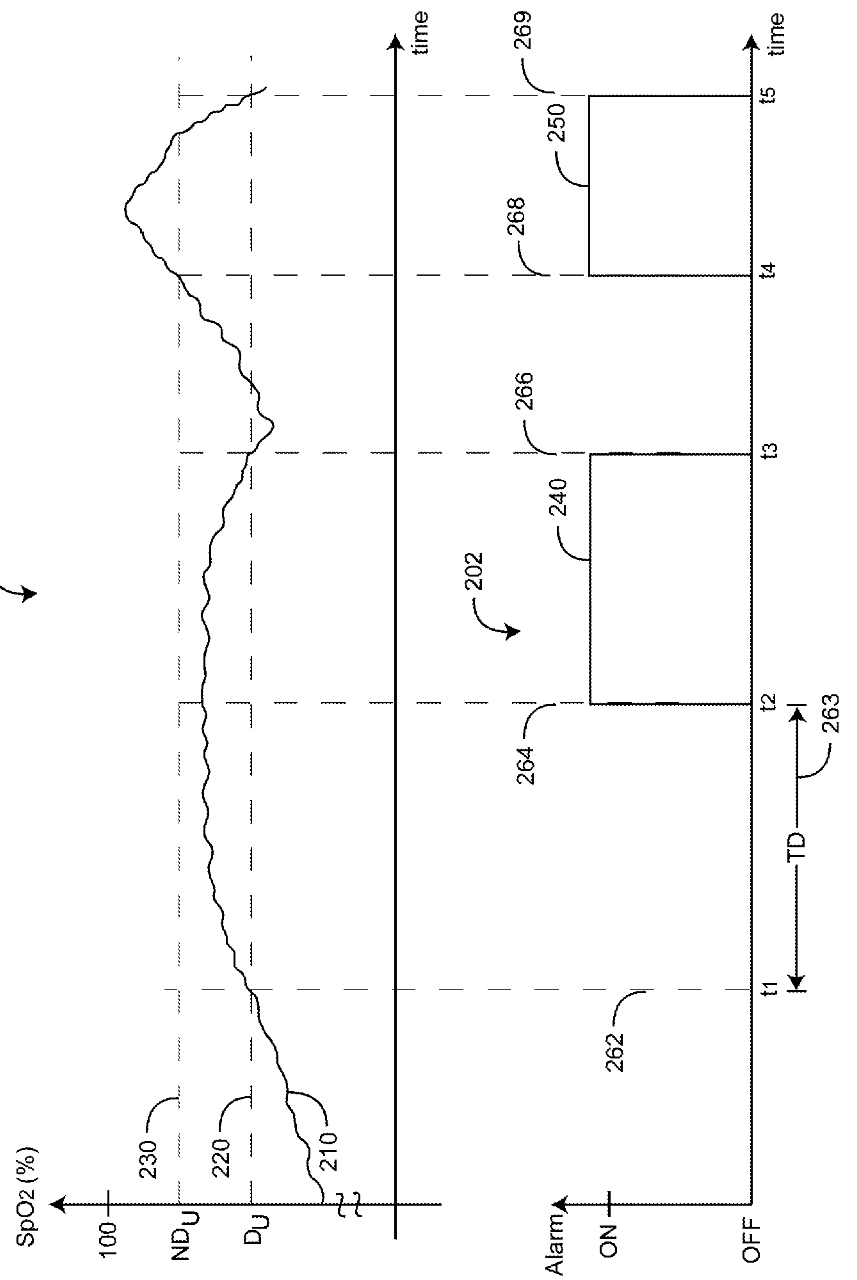
200
SpO2 (%)
100
ND_U
D_U
230
220
210
time
202
Alarm
ON
OFF
262
264
240
266
268
250
269
t1
t2
t3
t4
t5
TD
263
time

FIG. 2

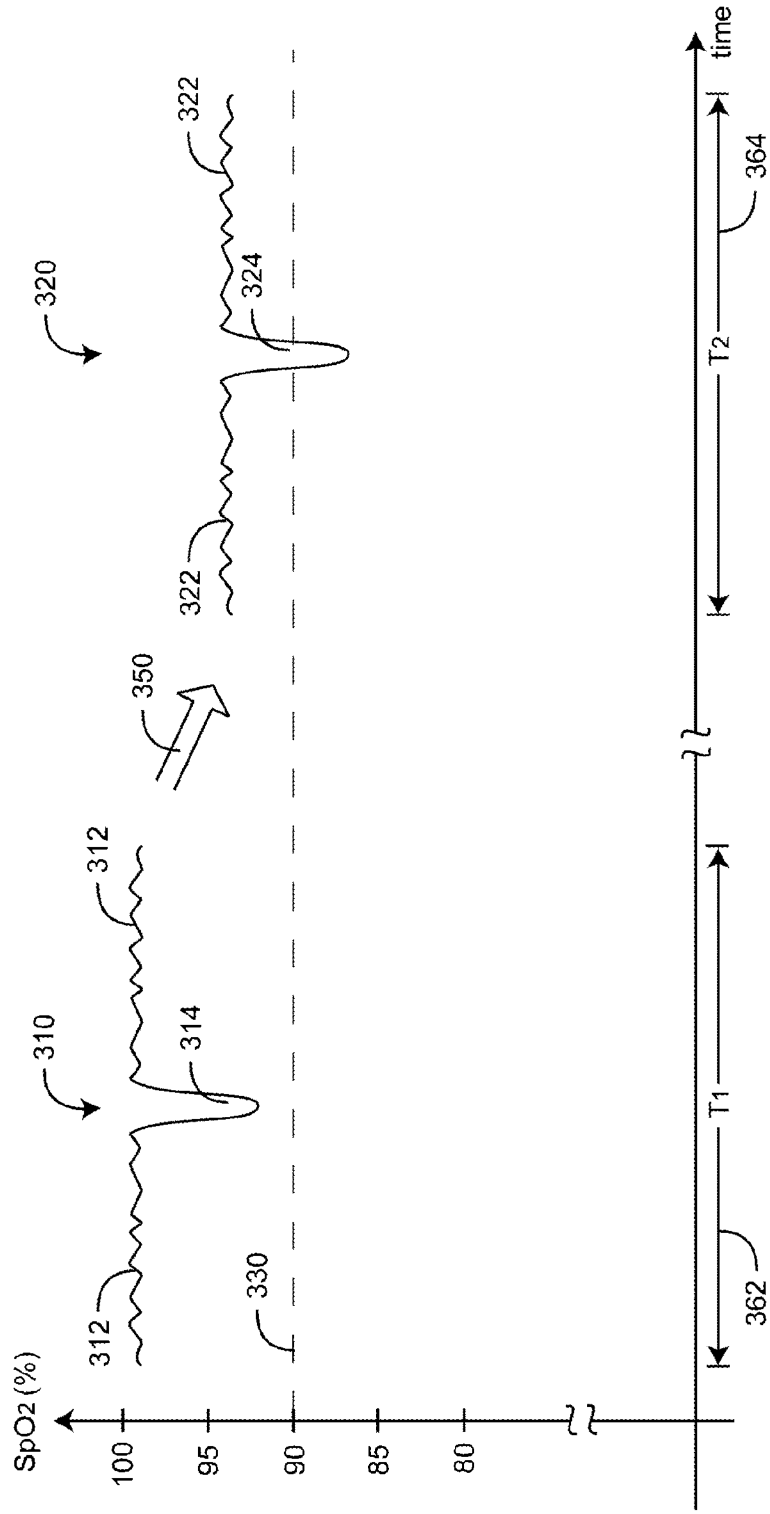
300
310
312
314
312
320
322
324
322
330
350
SpO2 (%)
100
95
90
85
80
time
T1
T2
362
364

FIG. 3

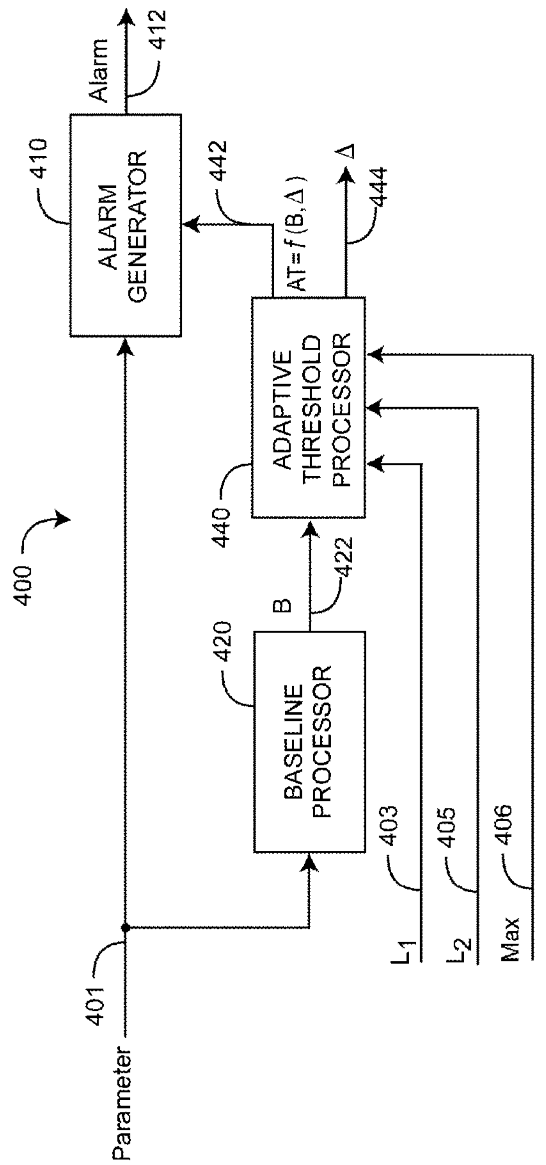
400
ALARM GENERATOR
410
Alarm
412
442
AT=f(B,Δ)
Δ
444
ADAPTIVE THRESHOLD PROCESSOR
440
BASELINE PROCESSOR
420
B
422
Parameter
401
403
405
406
L_1
L_2
Max

FIG. 4A

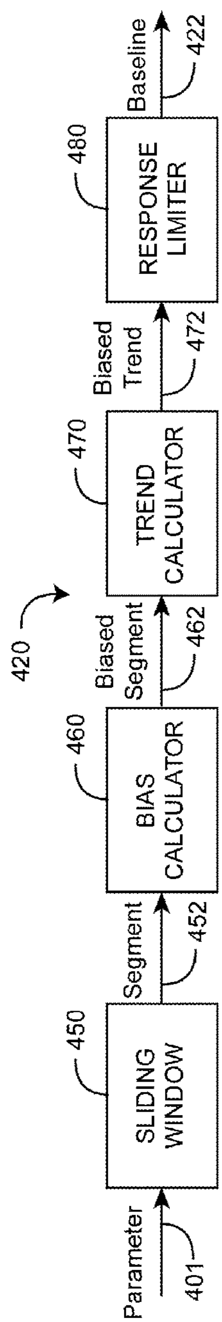
420
Parameter
401
SLIDING WINDOW
450
Segment
452
BIAS CALCULATOR
460
Biased Segment
462
TREND CALCULATOR
470
Biased Trend
472
RESPONSE LIMITER
480
Baseline
422

FIG. 4B

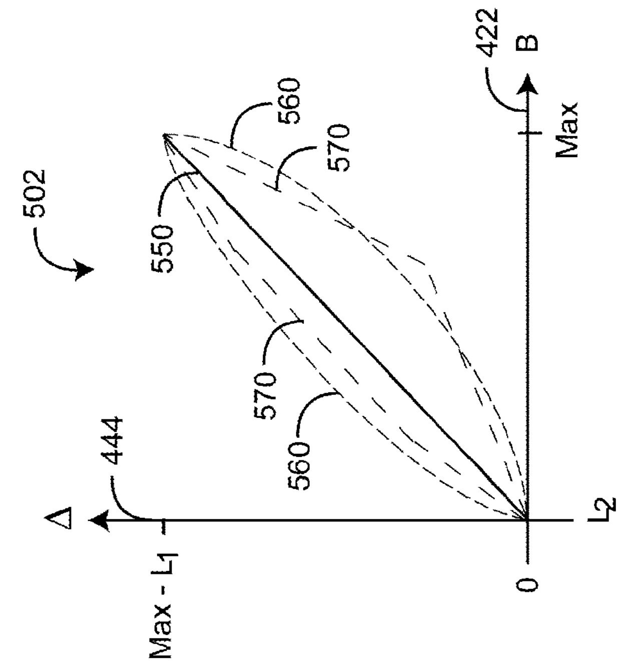
502
550
560
570
570
560
444
Δ
Max - L1
0
L2
Max
422
B

FIG. 5B

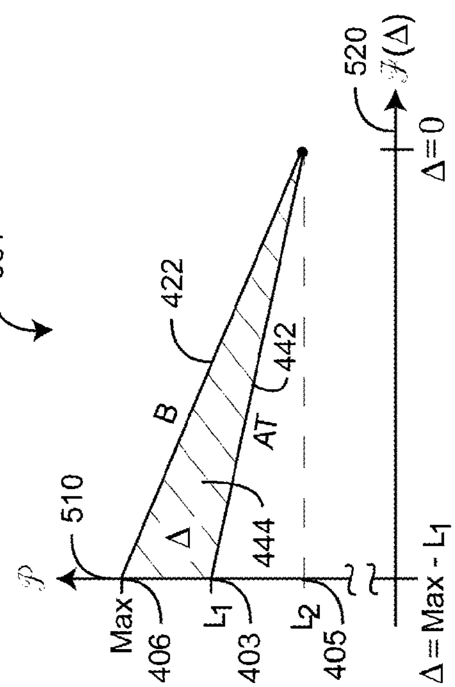
501
422
B
442
AT
444
Δ
510
Max
406
L1
403
L2
405
Δ=Max - L1
Δ=0
520

FIG. 5A

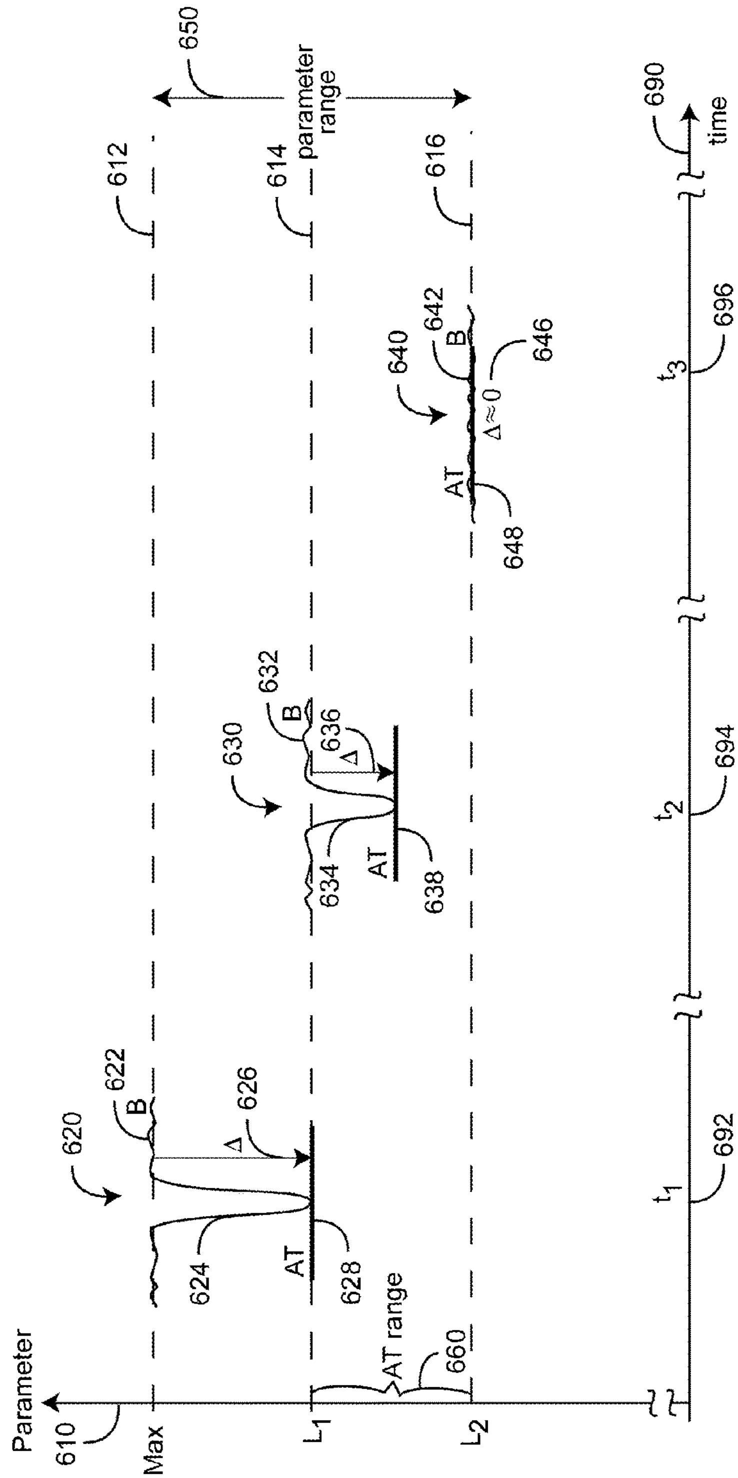
600
Parameter
610
Max
L_1
L_2
AT range
660
612
614
616
parameter range
650
time
690
620
622
B
624
626
Δ
AT
628
630
632
634
636
638
640
642
646
648
Δ≈0
t_1
t_2
t_3
692
694
696

FIG. 6

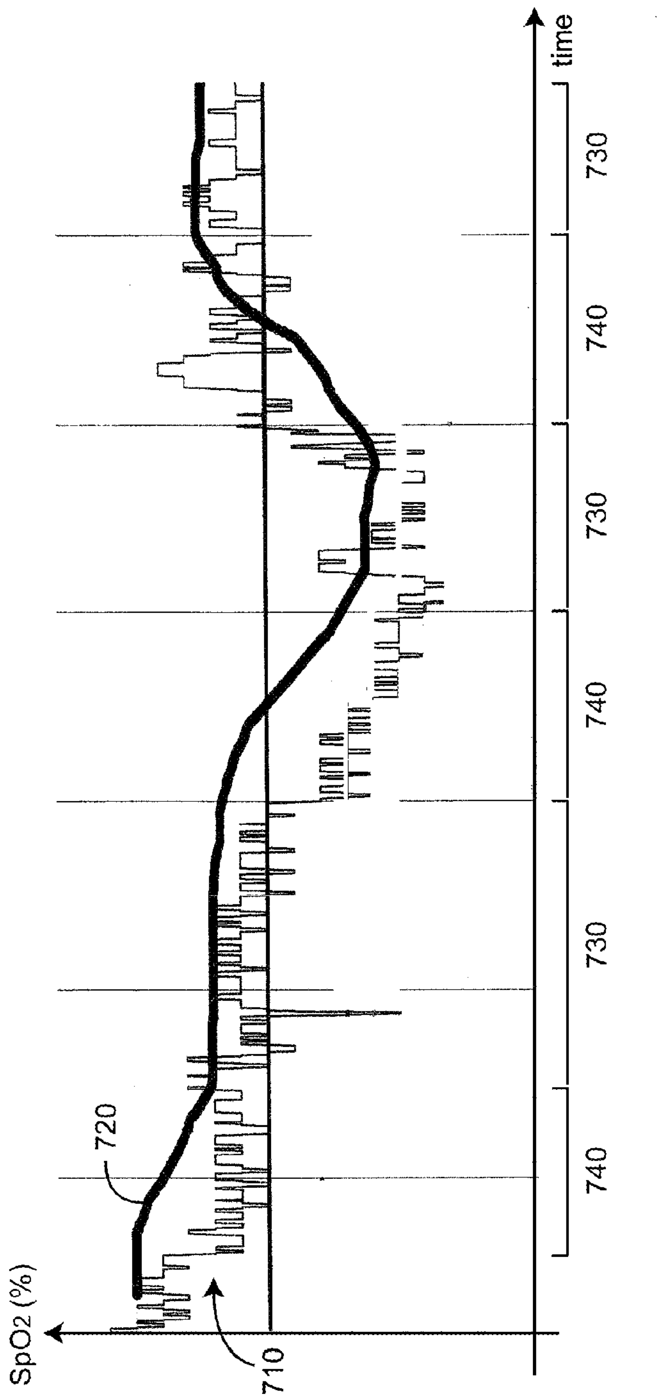

FIG. 7

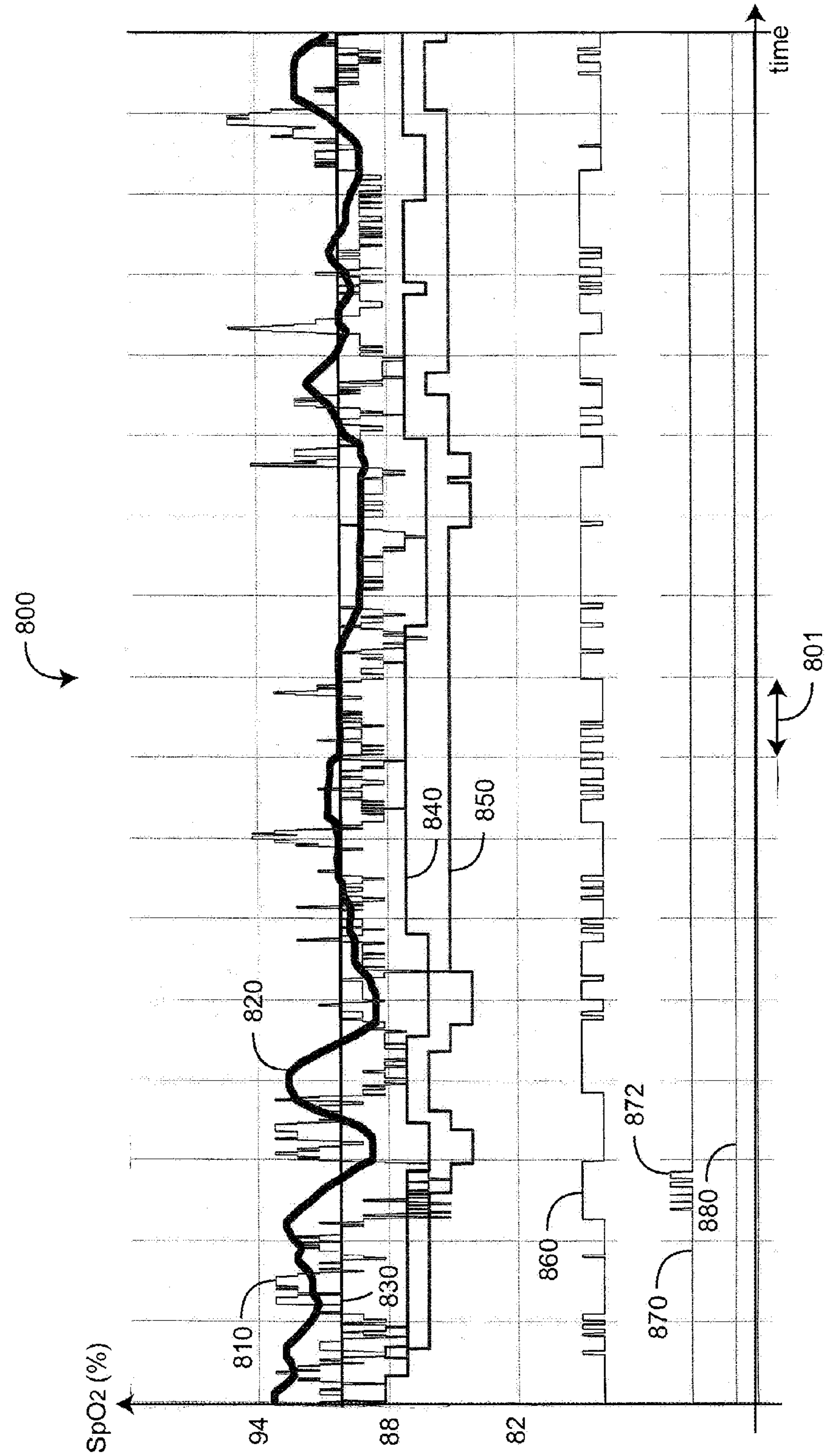

FIG. 8

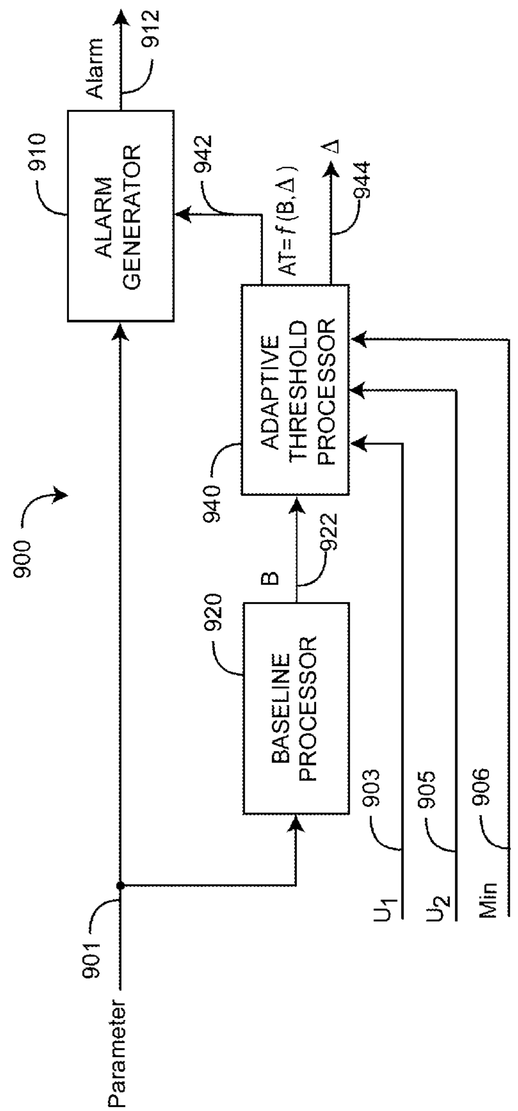
900
Parameter
901
ALARM GENERATOR
910
Alarm
912
942
BASELINE PROCESSOR
920
B
922
ADAPTIVE THRESHOLD PROCESSOR
940
AT = f (B, Δ)
Δ
944
U_1
903
U_2
905
Min
906

FIG. 9A

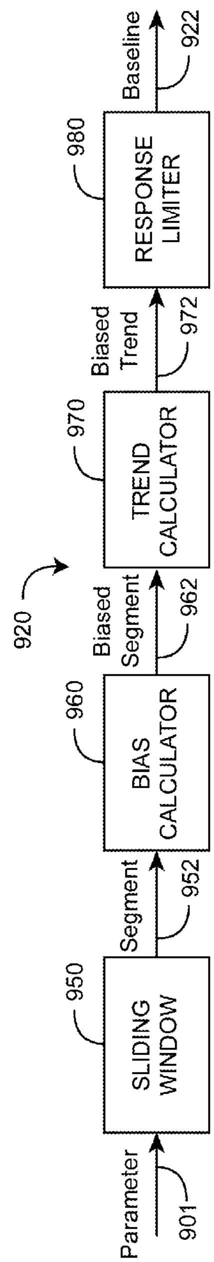
920
Parameter
901
SLIDING WINDOW
950
Segment
952
BIAS CALCULATOR
960
Biased Segment
962
TREND CALCULATOR
970
Biased Trend
972
RESPONSE LIMITER
980
Baseline
922

FIG. 9B

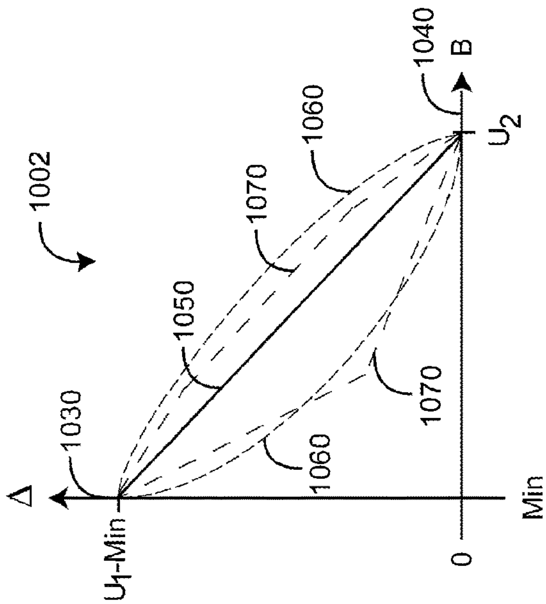

FIG. 10B

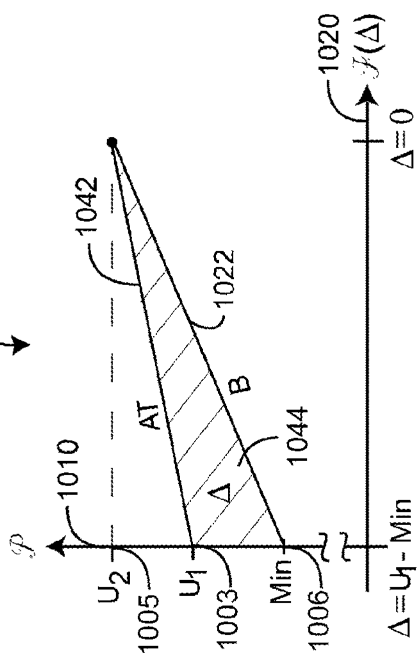

FIG. 10A

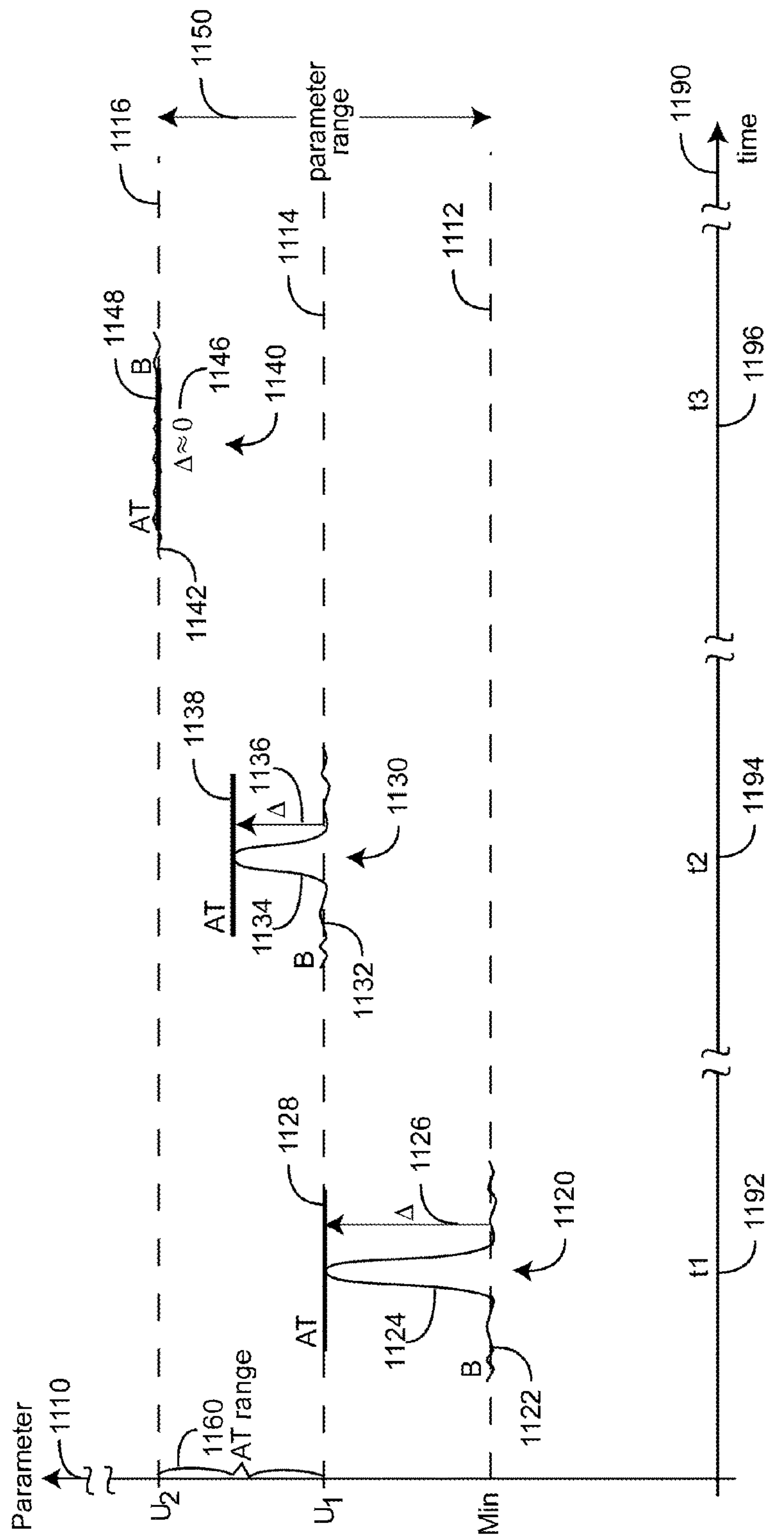
1100
Parameter
1110
U2
U1
Min
1160
AT range
1116
1114
1112
1150
parameter range
AT
B
1122
1124
1120
1126
Δ
1128
1132
1134
1130
1136
1138
1142
1140
Δ≈0
1146
1148
t1
t2
t3
1192
1194
1196
1190
time

FIG. 11

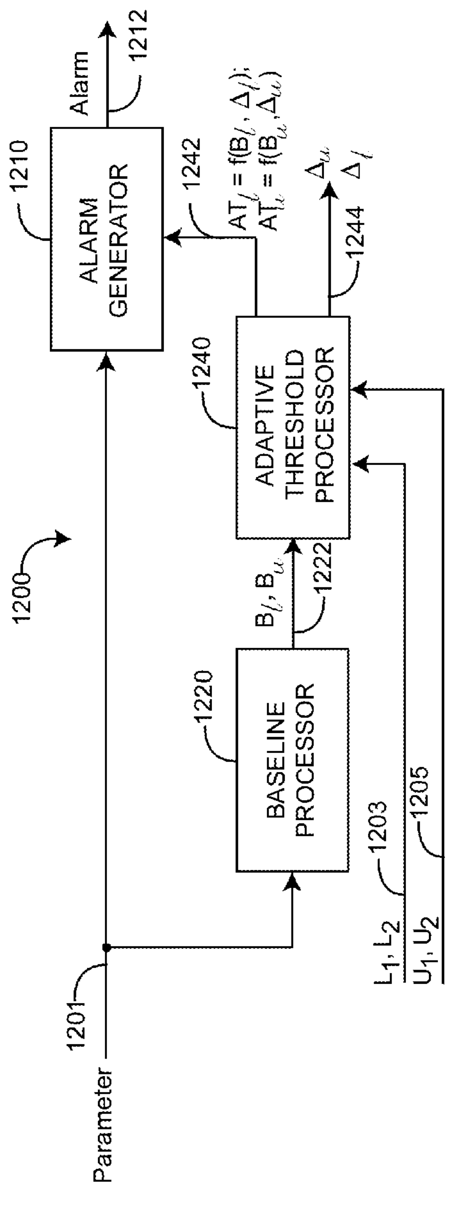

FIG. 12A

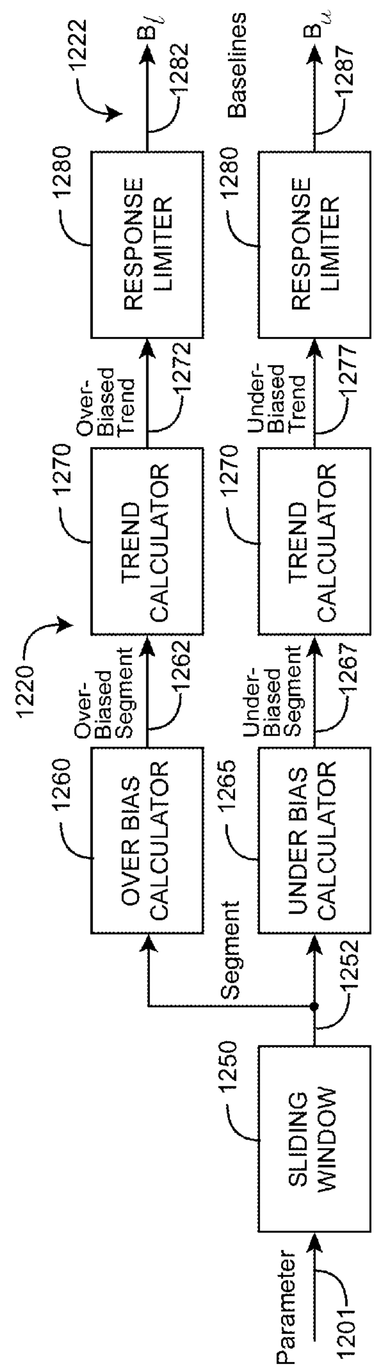

FIG. 12B

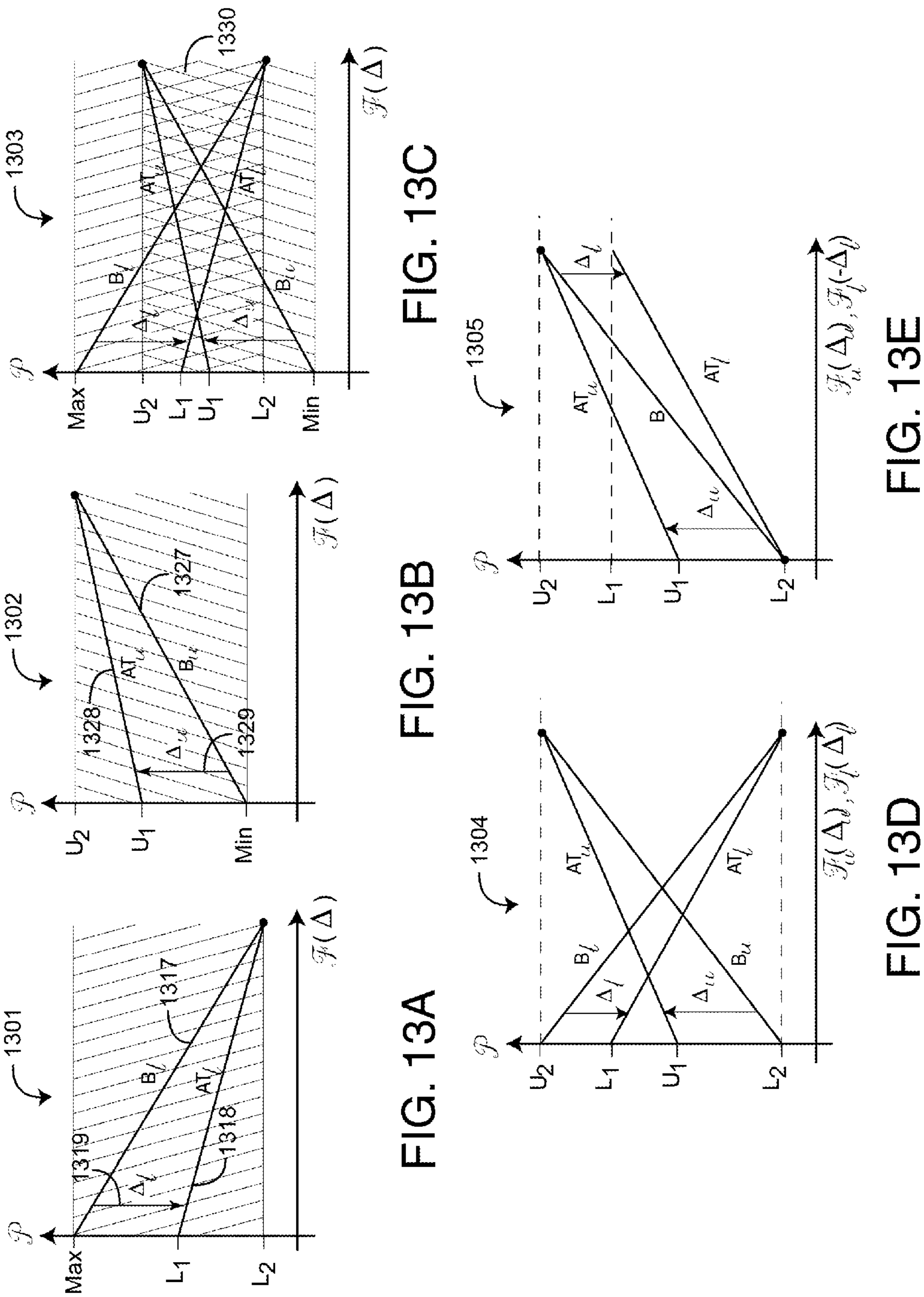

FIG. 13A

FIG. 13B

FIG. 13C

FIG. 13D

FIG. 13E

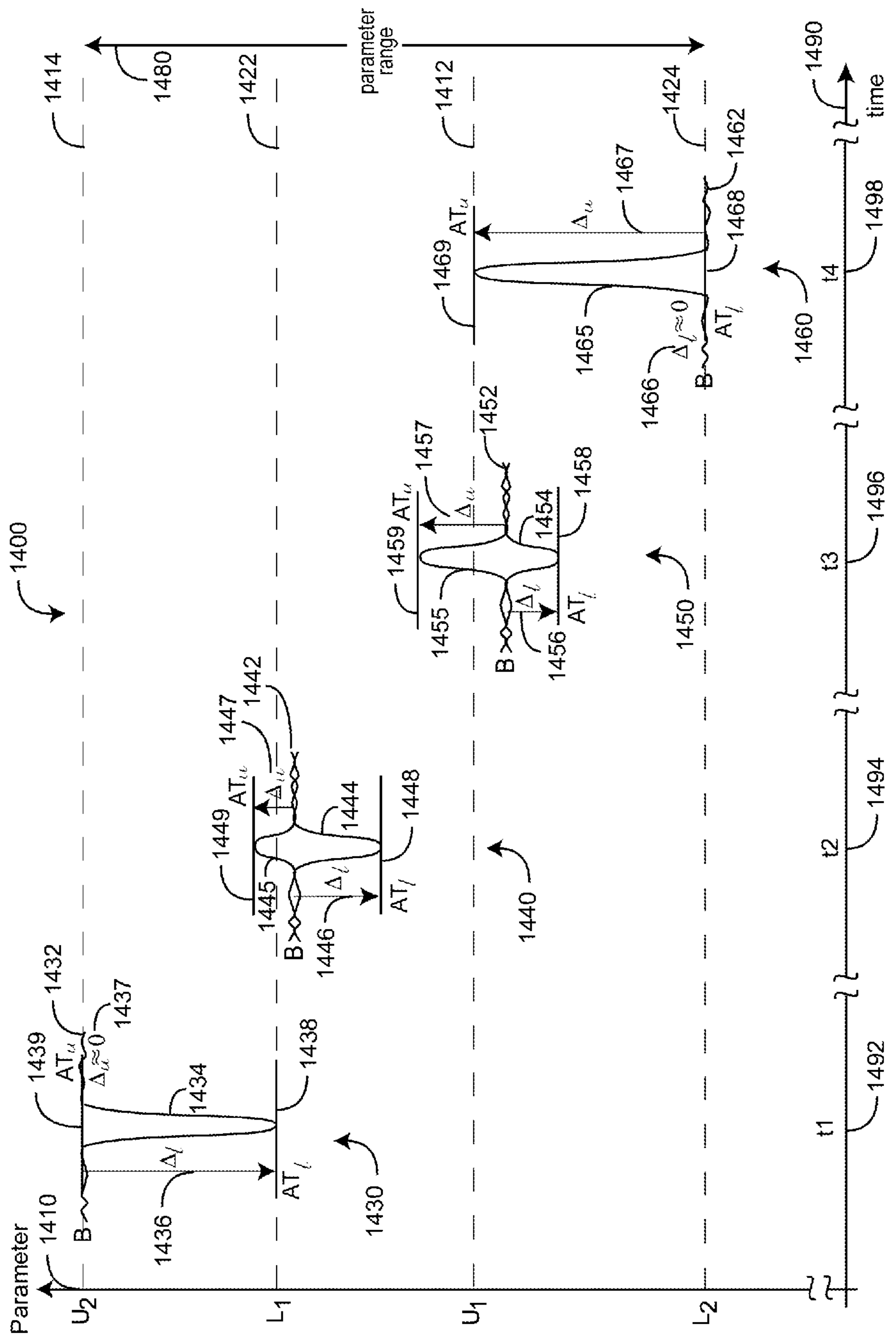
1400
Parameter
time
parameter range
U2
L1
U1
L2
t1
t2
t3
t4
1410
1412
1414
1422
1424
1430
1440
1450
1460
1480
1490
1492
1494
1496
1498

FIG. 14

ADAPTIVE ALARM SYSTEM

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

PRIORITY CLAIM TO RELATED PROVISIONAL APPLICATIONS

[The present application claims priority benefit under 35 U.S.C. §119(e) to] *This is an application for reissue of U.S. Pat. No. 9,775,570, issued on Oct. 3, 2017 and titled "Adaptive Alarm System," which is a continuation of* U.S. patent application Ser. No. 13/037,184, filed Feb. 18, 2011 titled Adaptive Alarm System; *which claims priority benefit under 35 U.S.C. § 119(e) to* Provisional Patent Application Ser. No. 61/309,419, filed Mar. 1, 2010 titled Adaptive Threshold Alarm System; and U.S. Provisional Patent Application Ser. No. 61/328,630, filed Apr. 27, 2010 titled Adaptive Alarm System; all of the above-cited provisional patent applications are hereby incorporated by reference herein. *More than one reissue application has been filed for the reissue of Pat. No. 9,775,570. The reissue applications are application Nos. 15/881,602 (the present application) and 16/184,908.*

BACKGROUND OF THE INVENTION

Pulse oximetry systems for measuring constituents of circulating blood have gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios. A pulse oximetry system generally includes an optical sensor applied to a patient, a monitor for processing sensor signals and displaying results and a patient cable electrically interconnecting the sensor and the monitor. A pulse oximetry sensor has light emitting diodes (LEDs), typically one emitting a red wavelength and one emitting an infrared (IR) wavelength, and a photodiode detector. The emitters and detector are typically attached to a finger, and the patient cable transmits drive signals to these emitters from the monitor. The emitters respond to the drive signals to transmit light into the fleshy fingertip tissue. The detector generates a signal responsive to the emitted light after attenuation by pulsatile blood flow within the fingertip. The patient cable transmits the detector signal to the monitor, which processes the signal to provide a numerical readout of physiological parameters such as oxygen saturation (SpO_2) and pulse rate.

SUMMARY OF THE INVENTION

Conventional pulse oximetry assumes that arterial blood is the only pulsatile blood flow in the measurement site. During patient motion, venous blood also moves, which causes errors in conventional pulse oximetry. Advanced pulse oximetry processes the venous blood signal so as to report true arterial oxygen saturation and pulse rate under conditions of patient movement. Advanced pulse oximetry also functions under conditions of low perfusion (small signal amplitude), intense ambient light (artificial or sunlight) and electrosurgical instrument interference, which are scenarios where conventional pulse oximetry tends to fail.

Advanced pulse oximetry is described in at least U.S. Pat. Nos. 6,770,028; 6,658,276; 6,157,850; 6,002,952; 5,769,785 and 5,758,644, which are assigned to Masimo Corporation ("Masimo") of Irvine, Calif. and are incorporated by reference herein. Corresponding low noise optical sensors are disclosed in at least U.S. Pat. Nos. 6,985,764; 6,813,511; 6,792,300; 6,256,523; 6,088,607; 5,782,757 and 5,638,818, which are also assigned to Masimo and are also incorporated by reference herein. Advanced pulse oximetry systems including Masimo SET® low noise optical sensors and read through motion pulse oximetry monitors for measuring SpO_2, pulse rate (PR) and perfusion index (PI) are available from Masimo. Optical sensors include any of Masimo LNOP®, LNCS®, SofTouch™ and Blue™ adhesive or reusable sensors. Pulse oximetry monitors include any of Masimo Rad-8®, Rad-5®, Rad®-5v or SatShare® monitors.

Advanced blood parameter measurement systems are described in at least U.S. Pat. No. 7,647,083, filed Mar. 1, 2006, titled Multiple Wavelength Sensor Equalization; U.S. Pat. No. 7,729,733, filed Mar. 1, 2006, titled Configurable Physiological Measurement System; U.S. Pat. Pub. No. 2006/0211925, filed Mar. 1, 2006, titled Physiological Parameter Confidence Measure and U.S. Pat. Pub. No. 2006/0238358, filed Mar. 1, 2006, titled Noninvasive Multi-Parameter Patient Monitor, all assigned to Masimo Laboratories, Irvine, Calif. (Masimo Labs) and all incorporated by reference herein. An advanced parameter measurement system that includes acoustic monitoring is described in U.S. Pat. Pub. No. 2010/0274099, filed Dec. 21, 2009, titled Acoustic Sensor Assembly, assigned to Masimo and incorporated by reference herein.

Advanced blood parameter measurement systems include Masimo Rainbow® SET, which provides measurements in addition to SpO_2, such as total hemoglobin (SpHb™) oxygen content (SpOC™), methemoglobin (SpMet®), carboxyhemoglobin (SpCO®) and PVI®. Advanced blood parameter sensors include Masimo Rainbow® adhesive, ReSposable™ and reusable sensors. Advanced blood parameter monitors include Masimo Radical-7™, Rad-87™ and Rad-57™ monitors, all available from Masimo. Advanced parameter measurement systems may also include acoustic monitoring such as acoustic respiration rate (RRa™) using a Rainbow Acoustic Sensor™ and Rad-87™ monitor, available from Masimo. Such advanced pulse oximeters, low noise sensors and advanced physiological parameter measurement systems have also gained rapid acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios.

FIGS. **1-3** illustrate problems and issues associated with physiological parameter measurement systems having fixed threshold alarm schemas. FIG. **1** illustrates a lower-limit, fixed-threshold alarm schema with respect to an oxygen saturation (SpO_2) parameter. Two alarm thresholds, D_L (delay) and ND_L (no delay), are defined. If oxygen saturation falls below D_L for a time delay greater than TD, an alarm is triggered. If oxygen saturation falls below ND_L an alarm is immediately triggered. D_L **120** is typically set around or somewhat above 90% oxygen saturation and ND_L **130** is typically set at 5% to 10% below D_L. For example, say a person's oxygen saturation **110** drops below D_L **120** at $t=t_1$ **162** and stays below D_L for at least a time delay TD **163**. This triggers a delayed alarm **140** at $t=t_2$ **164**, where $t_2=t_1+$

TD. The alarm **140** remains active until oxygen saturation **110** rises above D_L **120** at $t=t_3$ **166**. As another example, say that oxygen saturation **110** then drops below ND_L **130**, which triggers an immediate alarm **150** at t=t4 **168**. The alarm **150** remains active until oxygen saturation **110** rises above D_L **120** at $t=t_5$ **169**.

FIG. **2** illustrates an upper-limit, fixed-threshold alarm schema with respect to an oxygen saturation (SpO_2) parameter. This alarm scenario is particularly applicable to the avoidance of ROP (retinopathy of prematurity). Again, two alarm thresholds, D_U (delay) and ND_U (no delay), are defined. D_U **220** might be set at or around 85% oxygen saturation and ND_U **230** might be set at or around 90% oxygen saturation. For example, a neonate's oxygen saturation **210** rises above D_U **220** at $t=t_1$ **262** and stays above D_U for at least a time delay TD **263**. This triggers a delayed alarm **240** at $t=t_2$ **264**, where $t_2=t_1+TD$. The alarm **240** remains active until oxygen saturation **210** falls below D_U **220** at $t=t_3$ **166**. Oxygen saturation **210** then rises above ND_U **230**, which triggers an immediate alarm **250** at $t=t_4$ **268**. The alarm **250** remains active until oxygen saturation **210** falls below D_U **220** at $t=t_5$ **269**.

FIG. **3** illustrates a baseline drift problem with the fixed threshold alarm schema described above. A person's oxygen saturation is plotted on an oxygen saturation (SpO_2) versus time graph **300**. In particular, during a first time interval T_1 **362**, a person has an oxygen saturation **310** with a relatively stable "baseline" **312** punctuated by a shallow, transient desaturation event **314**. This scenario may occur after the person has been on oxygen so that baseline oxygen saturation is near 100%. Accordingly, with a fixed threshold alarm **330** set at, say, 90%, the transient event **314** does not trigger a nuisance alarm. However, the effects of oxygen treatments wear off over time and oxygen saturation levels drift downward **350**. In particular, during a second time interval T_2 **364**, a person has an oxygen saturation **320** with a relatively stable baseline **322**. The later baseline **322** is established at a substantially lower oxygen saturation than the earlier baseline **312**. In this scenario, a shallow, transient desaturation event **324** now exceeds the alarm threshold **330** and results in a nuisance alarm. After many such nuisance alarms, a caregiver may lower the alarm threshold **330** to unsafe levels or turn off alarms altogether, significantly hampering the effectiveness of monitoring oxygen saturation.

A fixed threshold alarm schema is described above with respect to an oxygen saturation parameter, such as derived from a pulse oximeter. However, problematic fixed threshold alarm behavior may be exhibited in a variety of parameter measurement systems that calculate physiological parameters related to circulatory, respiratory, neurological, gastrointestinal, urinary, immune, musculoskeletal, endocrine or reproductive systems, such as the circulatory and respiratory parameters cited above, as but a few examples.

An adaptive alarm system, as described in detail below, advantageously provides an adaptive threshold alarm to solve false alarm and missed true alarm problems associated with baseline drift among other issues. For example, for a lower limit embodiment, an adaptive alarm system adjusts an alarm threshold downwards when a parameter baseline is established at lower values. Likewise, for an upper limit embodiment, the adaptive alarm system adjusts an alarm threshold upwards in accordance with baseline drift so as to avoid nuisance alarms. In an embodiment, the rate of baseline movement is limited so as to avoid masking of transients. In an embodiment, the baseline is established along upper or lower portions of a parameter envelop so as to provide a margin of safety in lower limit or upper limit systems, respectively.

One aspect of an adaptive alarm system is responsive to a physiological parameter so as to generate an alarm threshold that adapts to baseline drift in the parameter and reduce false alarms without a corresponding increase in missed true alarms. The adaptive alarm system has a parameter derived from a physiological measurement system using a sensor in communication with a living being. A baseline processor calculates a parameter baseline from an average value of the parameter. Parameter limits specify an allowable range of the parameter. An adaptive threshold processor calculates an adaptive threshold from the parameter baseline and the parameter limits. An alarm generator is responsive to the parameter and the adaptive threshold so as to trigger an alarm indicative of the parameter crossing the adaptive threshold. The adaptive threshold is responsive to the parameter baseline so as to increase in value as the parameter baseline drifts to a higher parameter value and to decrease in value as the parameter baseline drifts to a lower parameter value.

In various embodiments, the baseline processor has a sliding window that identifies a time slice of parameter values. A trend calculator determines a trend from an average of the parameter values in the time slice. A response limiter tracks only the relatively long-term transitions of the trend. A bias calculator deletes the highest parameter values in the time slice or the lowest parameter values in the time slice so as to adjust the baseline to either a lower value or a higher value, respectively. The adaptive threshold becomes less response to baseline drift as the baseline approaches a predefined parameter limit. A first adaptive threshold is responsive to lower parameter limits and a second adaptive threshold is responsive to upper parameter limits. The alarm generator is responsive to both positive and negative transients from the baseline according to the first adaptive threshold and the second adaptive threshold. The first adaptive threshold is increasingly responsive to negative transients and the second adaptive threshold is decreasingly responsive to positive transients as the baseline trends toward lower parameter values.

Another aspect of an adaptive alarm system measures a physiological parameter, establishes a baseline for the parameter, adjusts an alarm threshold according to drift of the baseline and triggers an alarm in response to the parameter measurement crossing the alarm threshold. In various embodiments, the baseline is established by biasing a segment of the parameter, calculating a biased trend from the biased segment and restricting the transient response of the biased trend. The alarm threshold is adjusted by setting a parameter limit and calculating a delta difference between the alarm threshold and the baseline as a linear function of the baseline according to the parameter limit. The delta difference is calculated by decreasing delta as the baseline drifts toward the parameter limit and increasing delta as the baseline drifts away from the parameter limit. A parameter limit is set by selecting a first parameter limit in relation to a delayed alarm and selecting a second parameter limit in relation to an un-delayed alarm. A segment of the parameter is biased by windowing the parameter measurements, removing a lower value portion of the windowed parameter measurements and averaging a remaining portion of the windowed parameter measurements. An upper delta difference between an upper alarm threshold and the baseline is calculated and a lower delta difference between a lower alarm threshold and the baseline is calculated.

A further aspect of an adaptive alarm system has a baseline processor that inputs a parameter and outputs a baseline according to a trend of the parameter. An adaptive threshold processor establishes an alarm threshold at a delta difference from the baseline. An alarm generator triggers an alarm based upon a parameter transient from the baseline crossing the alarm threshold. In various embodiments, a trend calculator outputs a biased trend and the baseline is responsive to the biased trend so as to reduce the size of a transient that triggers the alarm. A response limiter reduces baseline movement due to parameter transients. The adaptive threshold processor establishes a lower alarm threshold below the baseline and an upper alarm threshold above the baseline so that the alarm generator is responsive to both positive and negative transients from the baseline. The baseline processor establishes a lower baseline biased above the parameter trend and an upper baseline biased below the parameter trend. The lower alarm threshold is increasingly responsive to negative transients and the upper alarm threshold is decreasingly responsive to positive transients as the baseline trends toward lower parameter values.

DESCRIPTION OF THE DRAWINGS

FIGS. **1-3** are exemplar graphs illustrating problems and issues associated with physiological parameter measurement systems having fixed threshold alarm schemas;

FIGS. **4**A-B are general block diagrams of an adaptive alarm system having lower parameter limits;

FIGS. **5**A-B are a graph of a physiological parameter versus delta space and a graph of delta versus baseline, respectively, illustrating the relationship between a baseline, a lower-limit adaptive threshold and a variable difference delta between the baseline and the adaptive threshold;

FIG. **6** is an exemplar graph of a physiological parameter versus time illustrating an adaptive alarm system having a lower-limit adaptive threshold;

FIG. **7** is a graph of oxygen saturation versus time illustrating a baseline for determining an adaptive threshold;

FIG. **8** is a graph of oxygen saturation versus time comparing adaptive-threshold alarm performance with fixed-threshold alarm performance;

FIGS. **9**A-B are general block diagrams of an adaptive alarm system having upper parameter limits;

FIGS. **10**A-B are a graph of a physiological parameter versus delta space and a graph of delta versus baseline, respectively, illustrating the relationship between a baseline, an upper-limit adaptive threshold and a variable delta difference between the baseline and the adaptive threshold;

FIG. **11** is an exemplar graph of a physiological parameter versus time illustrating an adaptive alarm system having an upper-limit adaptive threshold;

FIGS. **12**A-B are general block diagrams of an adaptive alarm system having both lower alarm limits and upper alarm limits;

FIGS. **13**A-E are physiological parameter versus delta space graphs illustrating a lower-limit adaptive threshold, an upper-limit adaptive threshold, and a combined lower- and upper-limit adaptive threshold in various delta spaces; and

FIG. **14** is an exemplar graph of a physiological parameter versus time illustrating an adaptive alarm system having both lower and upper alarm limits.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENTS

FIGS. **4**A-B illustrate an adaptive alarm system **400** embodiment having lower parameter limits L_1 and L_2. As

shown in FIG. **4**A, the adaptive alarm system **400** has parameter **401**, first limit (L_1) **403**, second limit (L_2) **405** and maximum parameter value (Max) **406** inputs and generates a corresponding alarm **412** output. The parameter **401** input is generated by a physiological parameter processor, such as a pulse oximeter or an advanced blood parameter processor described above, as examples. The adaptive alarm system **400** has an alarm generator **410**, a baseline processor **420**, and an adaptive threshold processor **440**. The alarm generator **410** has parameter **401** and adaptive threshold (AT) **442** inputs and generates the alarm **412** output accordingly. A baseline processor **420** has the parameter **401** input and generates a parameter baseline (B) **422** output. The baseline processor **420**, is described in detail with respect to FIG. **4**B, below. An adaptive threshold processor **440** has parameter baseline (B) **422**, L_1 **403**, L_2 **405** and Max **406** inputs and generates the adaptive threshold (AT) **442**. The adaptive threshold processor **440** is described in detail with respect to FIGS. **5**A-B, below.

As shown in FIG. **4**A, in an embodiment L_1 **403** and L_2 **405** may correspond to conventional fixed alarm thresholds with and without an alarm time delay, respectively. For an adaptive threshold schema, however, L_1 **403** and L_2 **405** do not determine an alarm threshold per se, but are reference levels for determining an adaptive threshold (AT) **442**. In an embodiment, L_1 **403** is an upper limit of the adaptive alarm threshold AT when the baseline is near the maximum parameter value (Max), and L_2 **405** is a lower limit of the adaptive alarm threshold, as described in detail with respect to FIGS. **5**A-B, below. In an exemplar embodiment when the parameter is oxygen saturation, L_1 **403** is set at or around 90% and L_2 **405** is set at 5 to 10% below L_1, i.e. at 85% to 80% oxygen saturation. Many other L_1 and L_2 values may be used for an adaptive threshold schema as described herein.

Also shown in FIG. **4**A, in an embodiment the alarm **412** output is triggered when the parameter **401** input falls below AT **442** and ends when the parameter **401** input rises above AT **442** or is otherwise cancelled. In an embodiment, the alarm **412** output is triggered after a time delay (TD), which may be fixed or variable. In an embodiment, the time delay (TD) is a function of the adaptive threshold (AT) **442**. In an embodiment, the time delay (TD) is zero when the adaptive threshold (AT) is at the second lower limit (L_2) **405**.

As shown in FIG. **4**B, a baseline processor **420** embodiment has a sliding window **450**, a bias calculator **460**, a trend calculator **470** and a response limiter **480**. The sliding window **450** inputs the parameter **401** and outputs a time segment **452** of the parameter **401**. In an embodiment, each window incorporates a five minute span of parameter values. The bias calculator **460** advantageously provides an upward shift in the baseline (B) **422** for an additional margin of error over missed true alarms. That is, a baseline **422** is generated that tracks a higher-than-average range of parameter values, effectively raising the adaptive threshold AT slightly above a threshold calculated based upon a true parameter average, as shown and described in detail with respect to FIGS. **7-8**, below. In an embodiment, the bias calculator **460** rejects a lower range of parameter values from each time segment **452** from the sliding window so as to generate a biased time segment **462**.

Also shown in FIG. **4**B, the trend calculator **470** outputs a biased trend **472** of the remaining higher range of parameter values in each biased segment **462**. In an embodiment, the biased trend **462** is an average of the values in the biased time segment **462**. In other embodiments, the biased trend **462** is a median or mode of the values in the biased time segment **462**. The response limiter **480** advantageously

limits the extent to which the baseline **422** output tracks the biased trend **472**. Accordingly, the baseline **422** tracks only relatively longer-lived transitions of the parameter, but does not track (and hence mask) physiologically significant parameter events, such as oxygen desaturations for a SpO_2 parameter to name but one example. In an embodiment, the response limiter **480** has a low pass transfer function. In an embodiment, the response limiter **480** is a slew rate limiter.

FIGS. **5**A-B further illustrate an adaptive threshold processor **440** (FIG. **4**A) having a baseline (B) **422** input and generating an adaptive threshold (AT) **442** output and a delta (Δ) **444** ancillary output according to parameter limits L_1 **403**, L_2 **405** and Max **406**, as described above. As shown in FIG. **5**A, as the baseline (B) **422** decreases (increases) the adaptive threshold (AT) **444** monotonically decreases (increases) between L_1 **403** and L_2 **405**. Further, as the baseline (B) **422** decreases (increases) the delta (Δ) **444** difference between the baseline (B) **422** and the adaptive threshold (AT) **442** monotonically decreases (increases) between Max−L_1 and zero.

As shown in FIG. **5**B, the relationship between the delta (Δ) **444** and the baseline (B) **444** may be linear **550** (solid line), non-linear **560** (small-dash lines) or piecewise-linear (large-dash lines), to name a few. In an embodiment, the adaptive threshold processor **440** (FIG. **4**A) calculates an adaptive threshold (AT) **442** output in response to the baseline (B) **422** input according to a linear relationship. In a linear embodiment, the adaptive threshold processor **440** (FIG. **4**A) calculates the adaptive threshold (AT) **442** according to EQS. 1-2:

$$\Delta = -\left(\frac{\text{Max} - L_1}{\text{Max} - L_2}\right)(\text{Max} - B) + (\text{Max} - L_1) \tag{1}$$

$$AT = B - \Delta \tag{2}$$

where Δ=Max−L_1 @ B=Max; Δ=0 @ B=L_2
and where AT=L_1 @ B=Max; AT=L_2 @ B=L_2, accordingly.

FIG. **6** illustrates the operational characteristics an adaptive alarm system **400** (FIG. **4**A) having parameter limits Max **612**, L_1 **614** and L_2 **616** and an alarm responsive to a baseline (B) **622**, **632**, **642**; an adaptive threshold (AT) **628**, **638**, **648**; and a corresponding Δ **626**, **636**, **646** according to EQS. 1-2, above. In particular, a physiological parameter **610** is graphed versus time **690** for various time segments t_1, t_2, t_3 **692-696**. The parameter range (PR) **650** is:

$$PR = \text{Max} - L_2 \tag{3}$$

and the adaptive threshold range (ATR) **660** is:

$$ATR = L_1 - L_2 \tag{4}$$

As shown in FIG. **6**, during a first time period t_1 **692**, a parameter segment **620** has a baseline (B) **622** at about Max **612**. As such, Δ **626**=Max−L_1 and the adaptive threshold (AT) **628** is at about L_1 **614**. Accordingly, a transient **624** having a size less than Δ **626** does not trigger the alarm **412** (FIG. **4**A).

Also shown in FIG. **6**, during a second time period t_2 **694**, a parameter segment **630** has a baseline (B) **632** at about L_1 **614**. As such, Δ **636** is less than Max−L_1 and the adaptive threshold (AT) **638** is between L_1 and L_2. Accordingly, a smaller transient **634** will trigger the alarm as compared to a transient **624** in the first time segment.

Further shown in FIG. **6**, during a third time period t_3 **696**, a parameter segment **640** has a baseline (B) **642** at about L_2 **616**. As such, Δ **646** is about zero and the adaptive threshold (AT) **648** is at about L_2. Accordingly, even a small negative transient will trigger the alarm. As such, the behavior of the alarm threshold AT **628**, **638**, **648** advantageously adapts to higher or lower baseline values so as to increase or decrease the size of negative transients that trigger or do not trigger the alarm **412** (FIG. **4**A).

FIG. **7** is a parameter versus time graph **700** illustrating the characteristics of an adaptive alarm system **400** (FIGS. **4**A-B), as described with respect to FIGS. **4-6**, above, where the parameter is oxygen saturation (SpO_2). The graph **700** has a SpO_2 trace **710** and a superimposed baseline trace **720**. The graph **700** also delineates tracking periods **730**, where the baseline **720** follows the upper portions of SpO_2 values, and lagging periods **740**, where the baseline **720** does not follow transient SpO_2 events. The tracking time periods **730** illustrate that the baseline **720** advantageously tracks at the higher range of SpO_2 values **710** during relatively stable (flat) periods, as described above. Lagging time periods **740** illustrate that the baseline **720** is advantageously limited in response to transient desaturation events so that significant desaturations fall below an adaptive threshold (not shown) and trigger an alarm accordingly.

FIG. **8** is a parameter versus time graph **800** illustrating characteristics of an adaptive alarm system **400** (FIGS. **4**A-B), as described with respect to FIGS. **4-6**, above, where the parameter is oxygen saturation (SpO_2). Vertical axis (SpO_2) resolution is 1%. The time interval **801** between vertical hash marks is five minutes. The graph **800** has a SpO_2 trace **810** and a baseline trace **820**. The graph **800** also has a fixed threshold trace **830**, a first adaptive threshold (AT) trace **840** and a second AT trace **850**. The graph **800** further has a fixed threshold alarm trace **860**, a first adaptive threshold alarm trace **870** and a second adaptive threshold alarm trace **880**. In this example, L_1 is 90% and L_2 is 85% for the first AT trace **840** and first AT alarm trace **870**. L_2 is 80% for a second AT trace **850** and a second AT alarm trace **880**. The fixed threshold **830** results in many nuisance alarms **860**. By comparison, the adaptive threshold alarm with L_2=85% has just one time interval of alarms **872** during a roughly 6% desaturation period (from 92% to 86%). The adaptive threshold alarm with L_2=80%, has no alarms during the 1 hour 25 minute monitoring period.

FIGS. **9**A-B illustrate an adaptive alarm system **900** embodiment having upper parameter limits U_1 and U_2. As shown in FIG. **9**A, the adaptive alarm system **900** has parameter **901**, first limit (U_1) **903**, second limit (U_2) **905** and minimum parameter value (Min) **906** inputs and generates a corresponding alarm **912** output. The parameter **901** input is generated by a physiological parameter processor, such as a pulse oximeter or an advanced blood parameter processor described above, as examples. The adaptive alarm system **900** has an alarm generator **910**, a baseline processor **920**, and an adaptive threshold processor **940**. The alarm generator **910** has parameter **901** and adaptive threshold (AT) **942** inputs and generates the alarm **912** output accordingly. A baseline processor **920** has the parameter **901** input and generates a parameter baseline (B) **922** output. The baseline processor **920**, is described in detail with respect to FIG. **9**B, below. An adaptive threshold processor **940** has parameter baseline (B) **922**, U_1 **903**, U_2 **905** and Min **906** inputs and generates the adaptive threshold (AT) **942**. The adaptive threshold processor **940** is described in detail with respect to FIGS. **10**A-B, below.

As shown in FIG. **9**A, in an embodiment U_1 **903** and U_2 **905** may correspond to conventional fixed alarm thresholds with and without an alarm time delay, respectively. For an adaptive threshold schema, however, U_1 **903** and U_2 **905** do

not determine an alarm threshold per se, but are reference levels for determining an adaptive threshold (AT) **942**. In an embodiment, U_1 **903** is a lower limit of the adaptive alarm threshold AT when the baseline is near the minimum parameter value (Min), and U_2 **905** is an upper limit of the adaptive alarm threshold, as described in detail with respect to FIGS. **10**A-B, below. In an exemplar embodiment when the parameter is oxygen saturation, U_1 **903** is set at or around 85% and U_2 **905** is set at or around 90% oxygen saturation. Many other U_1 and U_2 values may be used for an adaptive threshold schema as described herein.

Also shown in FIG. **9**A, in an embodiment the alarm **912** output is triggered when the parameter **901** input rises above AT **942** and ends when the parameter **901** input falls below AT **942** or is otherwise cancelled. In an embodiment, the alarm **912** output is triggered after a time delay (TD), which may be fixed or variable. In an embodiment, the time delay (TD) is a function of the adaptive threshold (AT) **942**. In an embodiment, the time delay (TD) is zero when the adaptive threshold (AT) is at the second upper limit (U_2) **905**.

As shown in FIG. **9**B, a baseline processor **920** embodiment has a sliding window **950**, a bias calculator **960**, a trend calculator **970** and a response limiter **980**. The sliding window **950** inputs the parameter **901** and outputs a time segment **952** of the parameter **901**. In an embodiment, each window incorporates a five minute span of parameter values. The bias calculator **960** advantageously provides a downward shift in the baseline (B) **922** for an additional margin of error over missed true alarms. That is, a baseline **922** is generated that tracks a lower-than-average range of parameter values, effectively lowering the adaptive threshold AT slightly below a threshold calculated based upon a true parameter average. In an embodiment, the bias calculator **960** rejects an upper range of parameter values from each time segment **952** from the sliding window so as to generate a biased time segment **962**.

Also shown in FIG. **9**B, the trend calculator **970** outputs a biased trend **972** of the remaining lower range of parameter values in each biased segment **962**. In an embodiment, the biased trend **962** is an average of the values in the biased time segment **962**. In other embodiments, the biased trend **962** is a median or mode of the values in the biased time segment **962**. The response limiter **980** advantageously limits the extent to which the baseline **922** output tracks the biased trend **972**. Accordingly, the baseline **922** tracks only relatively longer-lived transitions of the parameter, but does not track (and hence mask) physiologically significant parameter events, such as oxygen desaturations for a SpO_2 parameter to name but one example. In an embodiment, the response limiter **980** has a low pass transfer function. In an embodiment, the response limiter **980** is a slew rate limiter.

FIGS. **10**A-B further illustrate an adaptive threshold processor **940** (FIG. **9**A) having a baseline (B) **922** input and generating an adaptive threshold (AT) **942** output and a delta (Δ) **944** ancillary output according to parameter limits U_1 **903**, U_2 **905** and Min **906**, as described above. As shown in FIG. **10**A, as the baseline (B) **922** decreases (increases) the adaptive threshold (AT) **944** monotonically decreases (increases) between U_1 **903** and U_2 **905**. Further, as the baseline (B) **922** decreases (increases) the delta (Δ) **944** difference between the baseline (B) **922** and the adaptive threshold (AT) **942** monotonically decreases (increases) between Min−U_1 and zero.

As shown in FIG. **10**B, the relationship between the delta (Δ) **944** and the baseline (B) **944** may be linear **550** (solid line), non-linear **560** (small-dash lines) or piecewise-linear (large-dash lines), to name a few. In an embodiment, the adaptive threshold processor **940** (FIG. **9**A) calculates an adaptive threshold (AT) **942** output in response to the baseline (B) **922** input according to a linear relationship. In a linear embodiment, the adaptive threshold processor **940** (FIG. **9**A) calculates the adaptive threshold (AT) **942** according to EQS. 5-6:

$$\Delta = -\left(\frac{U_1 - \text{Min}}{U_2 - \text{Min}}\right)(B - \text{Min}) + (U_1 - \text{Min}) \tag{5}$$

$$AT=B+\Delta \tag{6}$$

where $\Delta=U_1-\text{Min}$ @ B=Min; Δ=0 @ $B=U_2$ and where $AT=U_1$ @ B=Min; $AT=U_2$ @ $B=U_2$, accordingly.

FIG. **11** illustrates the operational characteristics an adaptive alarm system **900** (FIG. **9**A) having parameter limits Min **1112**, U_1 **1114** and U_2 **1116** and an alarm responsive to a baseline (B) **1122**, **1132**, **1142**; an adaptive threshold (AT) **1128**, **1138**, **1148**; and a corresponding Δ **1126**, **1136**, **1146** according to EQS. 5-6, above. In particular, a physiological parameter **1110** is graphed versus time **1190** for various time segments t_1, t_2, t_3 **1192-1196**. The parameter range (PR) **1150** is:

$$PR=U_2-\text{Min} \tag{7}$$

and the adaptive threshold range (ATR) **1160** is:

$$ATR=U_2-U_1 \tag{8}$$

As shown in FIG. **11**, during a first time period t_1 **1192**, a parameter segment **1120** has a baseline (B) **1122** at about Min **1112**. As such, Δ **1126**=U_1−Min and the adaptive threshold (AT) **1128** is at about U_1 **1114**. Accordingly, a transient **1124** having a size less than Δ **1126** does not trigger the alarm **912** (FIG. **9**A).

Also shown in FIG. **11**, during a second time period t_2 **1194**, a parameter segment **1130** has a baseline (B) **1132** at about U_1 **1114**. As such, Δ **1136** is less than U_1−Min and the adaptive threshold (AT) **1138** is between U_1 and U_2. Accordingly, a smaller transient **1134** will trigger the alarm as compared to a transient **1124** in the first time segment.

Further shown in FIG. **11**, during a third time period t_3 **1196**, a parameter segment **1140** has a baseline (B) **1142** at about U_2 **1116**. As such, Δ **1146** is about zero and the adaptive threshold (AT) **1148** is at about U_2. Accordingly, even a small positive transient will trigger the alarm. As such, the behavior of the alarm threshold AT **1128**, **1138**, **1148** advantageously adapts to higher or lower baseline values so as to increase or decrease the size of positive transients that trigger or do not trigger the alarm **912** (FIG. **9**A).

FIGS. **12**A-B illustrate an adaptive alarm system **1200** embodiment having lower limits L_1, L_2 **1203**, such as described with respect to FIGS. **4**A-B above, or upper limits U_1, U_2 **1205** such as described with respect to FIGS. **9**A-B above, or both. As shown in FIG. **12**A, the adaptive alarm system **1200** has parameter **1201**, lower limit **1203** and upper limit **1205** inputs and generates a corresponding alarm **1212** output. The parameter **1201** input is generated by a physiological parameter processor, such as a pulse oximeter or an advanced blood parameter processor described above, as examples. The adaptive alarm system **1200** has an alarm generator **1210**, a baseline processor **1220** and an adaptive threshold processor **1240**. The alarm generator **1210** has parameter **1201** and adaptive threshold (AT) **1242** inputs and generates the alarm **1212** output accordingly. A baseline processor **1220** has the parameter **1201** input and generates

one or more parameter baseline **1222** outputs. The baseline processor **1220**, is described in detail with respect to FIG. **12**B, below. An adaptive threshold processor **1240** has parameter baseline **1222**, lower limit L_1, L_2 **1203** and upper limit U_1, U_2 **1205** inputs and generates lower and upper adaptive threshold AT_l, AT_u **1242** outputs. The adaptive threshold processor **1240** also generates ancillary upper and lower delta **1244** outputs. The adaptive threshold processor **1240** is described in detail with respect to FIGS. **13**A-E, below.

As shown in FIG. **12**A, in an embodiment L_1, L_2 **1203** and U_1, U_2 **1205** may correspond to conventional fixed alarm thresholds with an alarm delay (L_1, U_1) and without an alarm delay (L_2, U_2). For an adaptive threshold schema, however, these limits **1203**, **1205** do not determine an alarm threshold per se, but are reference levels for determining lower and upper adaptive thresholds AT_l, AT_u **1242**.

Also shown in FIG. **12**A, in an embodiment the alarm **1212** output is triggered when the parameter **1201** input falls below AT_l **1242** and ends when the parameter **1201** input rises above AT_l **1242** or the alarm is otherwise cancelled. Further, the alarm **1212** output is triggered when the parameter **1201** input rises above AT_u **1242** and ends when the parameter **1201** input falls below AT_u **1242** or the alarm is otherwise cancelled. In an embodiment, the alarm **1212** output is triggered after a time delay (TD), which may be fixed or variable. In an embodiment, the time delay (TD) is a function of the adaptive thresholds (AT_l, AT_u) **1242**. In an embodiment, the time delay (TD) is zero when the lower adaptive threshold (AT_l) **1242** is at the second lower limit (L_2) **1203** or when the upper adaptive alarm threshold AT_u **1242** is at the second upper limit (U_2) **1205**.

As shown in FIG. **12**B, a baseline processor **1220** embodiment has a sliding window **1250**, an over-bias calculator **1260**, an under-bias calculator **1265**, trend calculators **1270** and response limiters **1280**. The sliding window **1250** inputs the parameter **1201** and outputs a time segment **1252** of the parameter **1201**. In an embodiment, each window incorporates a five minute span of parameter **1201** values.

Also shown in FIG. **12**B, the over-bias calculator **1260** advantageously provides an upward shift in the lower baseline (B_l) **1282** for an additional margin of error over missed lower true alarms. That is, a lower baseline (B_l) **1282** is generated that tracks a higher-than-average range of parameter values, effectively raising the lower adaptive threshold AT_l slightly above a threshold calculated based upon a true parameter average. In an embodiment, the over-bias calculator **1260** rejects a lower range of parameter values from each time segment **1252** of the sliding window **1250** so as to generate an over-biased time segment **1262**.

Further shown in FIG. **12**B, the under-bias calculator **1265** advantageously provides a downward shift in the upper baseline (B_u) **1287** for an additional margin of error over missed upper true alarms. That is, an upper baseline (B_u) **1287** is generated that tracks a lower-than-average range of parameter values, effectively lowering the upper adaptive threshold AT_u slightly below a threshold calculated based upon a true parameter average. In an embodiment, the under-bias calculator **1267** rejects an upper range of parameter values from each time segment **1252** of the sliding window **1250** so as to generate an under-biased time segment **1267**.

Additionally shown in FIG. **12**B, the trend calculator **1270** outputs an over-biased trend **1272** of the remaining higher range of parameter values in each over-biased segment **1262**. Further, the trend calculator **1270** outputs an under-biased trend **1277** of the remaining lower range of parameter values in each under-biased segment **1267**. In an embodiment, the biased trends **1272**, **1277** are each an average of the values in the corresponding biased time segments **1262**, **1267**. In other embodiments, the biased trends **1272**, **1277** are each a median or mode of the values in the corresponding biased time segments **1262**, **1267**. The response limiter **1280** advantageously limits the extent to which the baseline **1222** outputs track the biased trends **1272**, **1277**. Accordingly, the baseline **1222** outputs track only relatively longer-lived transitions of the parameter **1201**, but do not track (and hence mask) physiologically significant parameter events. In an embodiment, the response limiter **1280** has a low pass transfer function. In an embodiment, the response limiter **1280** is a slew rate limiter.

FIGS. **13**A-E illustrate parameter (P) operating ranges and ideal ranges in view of both lower and upper parameter limits. As shown in FIG. **13**A, as the baseline (B_l) **1317** decreases (increases) the adaptive threshold (AT_l) **1318** monotonically decreases (increases) between L_1 and L_2. Further, as the baseline (B_l) **1317** decreases (increases) the delta (Δ_l) **1319** difference between the baseline (B_l) **1317** and the adaptive threshold (AT_l) **1318** monotonically decreases (increases) between Max$-L_1$ and 0.

As shown in FIG. **13**B, as the baseline (B_u) **1327** increases (decreases) the adaptive threshold (AT_u) **1328** monotonically increases (decreases) between U_1 and U_2. Further, as the baseline (B_u) **1327** increases (decreases) the delta (Δ_u) **1329** difference between the adaptive threshold (AT_u) **1328** and the baseline (B_u) **1327** monotonically decreases (increases) between Min$-U_1$ and 0.

As shown in FIG. **13**C, combining FIGS. **13**A-B, the parameter (P) operating range is bounded by the overlapping regions of **13**A and **13**B **1330** having an upper bound of U_2 and a lower bound of L_2. In particular, L_1, L_2 are the upper and lower limits of the lower adaptive alarm threshold AT_l; and U_2, U_1 are the upper and lower limits of the upper adaptive alarm threshold AT_u.

FIG. **13**D illustrates parameter (P) versus the overlapping independent delta domains F_u, F_l for upper and lower baselines B_u, B_l; adaptive thresholds AT_u, AT_l and deltas Δ_u, Δ_l, based upon FIGS. **13**A-C. FIG. **13**E illustrates parameter (P) versus the overlapping independent delta domains F_u, F_l (reversed); for upper and lower baselines B_u, B_l; adaptive thresholds AT_u, AT_l and deltas Δ_u, Δ_l,

As shown in FIG. **13**E, the equations for bi-lateral adaptive thresholds are:

$$\Delta_u = -\left(\frac{U_1 - L_2}{U_2 - L_2}\right)(B - L_2) + (U_1 - L_2) \tag{9}$$

$$AT_u = B + \Delta_u \tag{10}$$

where $\Delta_u = U_1 - L_2$ @ $B = L_2$; and $\Delta_u = 0$ @ $B = U_2$; and where $AT_u = U_1$ @ $B = L_2$; and $AT_u = U_2$ @ $B = U_2$. Further:

$$\Delta_l = \left(\frac{U_2 - L_1}{U_2 - L_2}\right)(B - L_2) \tag{11}$$

$$AT_l = B - \Delta_l \tag{12}$$

where $\Delta_l = U_2 - L_1$ @ $B = U_2$; and $\Delta_l = 0$ @ $B = L_2$; and where $AT_l = L_1$ @ $B = U_2$; $AT_l = L_2$ @ $B = L_2$.

Although shown as a linear relationship, in general:

$$\Delta_l=f_1(B);\Delta_u=f_2(B)$$

That is, Δ_l and Δ_u can each be a linear function of B, a non-linear function of B or a piecewise linear function of B, to name a few, in a manner similar to that described with respect to FIGS. **5**B and **10**B, above.

FIGS. **14**A-B illustrate the operational characteristics an adaptive alarm system **1200** (FIGS. **12**A-B) having upper limits U_1, U_2 **1412**, **1414** and lower limits L_1, L_2 **1422**, **1424**. An alarm **1212** (FIG. **12**A) output is responsive to a baseline (B) **1432**, **1442**, **1452**, **1462**; an upper delta (Δ_u) **1437**, **1447**, **1457**, **1467**; and a corresponding upper adaptive threshold (AT_u) **1439**, **1449**, **1459**, **1469**, according to EQS. 9-10, above. Further, the alarm **1212** (FIG. **12**A) output is responsive to a lower delta (Δ_l) **1436**, **1446**, **1456**, **1466** and a corresponding lower adaptive threshold (AT_l) **1438**, **1448**, **1458**, **1468**, according to EQS. 11-12, above.

As shown in FIGS. **14**A-B, a physiological parameter **1410** is graphed versus time **1490** for various time segments t_1, t_2, t_3, t_4 **1492-1498**. The parameter range (PR) **1480** is:

$$PR=U_2-L_2 \tag{13}$$

the lower adaptive threshold AT_l range is:

$$ATR_l=L_1-L_2 \tag{14}$$

the upper adaptive threshold AT_U range is:

$$ATR_l=U_2-U_1 \tag{15}$$

As shown in FIG. **14**A, during a first time period t_1 **1492**, a parameter segment **1430** has a baseline (B) **1432** at about U_2 **1414**. As such, Δ_l **1436**$=U_2-L_1$; Δ_u **1437**$=0$; AT_l **1438**$=L_1$; AT_u **1439**$=U_2$. Accordingly, a negative transient **1434** having a size less than U_2-L_1 does not trigger an alarm.

Also shown in FIG. **14**A, during a second time period t_2 **1494**, a parameter segment **1440** has a baseline (B) **1442** less than U_2. As such, Δ_l **1446** is less than U_1-L_1 and the adaptive threshold (AT_u) **1447** is between U_1 and U_2. Accordingly, a smaller negative transient **1444** will trigger the alarm as compared to the negative transient **1434** in the first time segment **1430**.

Further shown in FIG. **14**A, during a third time period t_3 **1496**, a parameter segment **1450** has a baseline (B) **1452** less than U_1 **1412**. As such, a smaller negative transient **1454** will trigger the alarm as compared to the negative transient **1444** in the second time segment **1440**. However, a larger positive transient **1455** is needed to trigger the alarm as compared to the positive transient **1445** in the second time segment **1440**.

Additionally shown in FIG. **14**A, during a fourth time period t_4 **1460**, a parameter segment **1460** has a baseline (B) **1462** at about L_2 **1424**. As such, Δ_l **1466**$=0$; Δ_u **1467**$=U_1-L_2$; AT_l **1468**$=L_2$; AT_u **1469**$=U_1$. Accordingly, a positive transient **1465** having a size less than U_1-L_2 does not trigger an alarm.

An adaptive alarm system has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.

What is claimed is:

1. A system for reducing electronic alarms in a medical patient monitoring system, the system comprising:

an optical sensor configured to transmit optical radiation into a tissue site of a patient and detect attenuated optical radiation indicative of at least one physiological parameter of a patient; and

one or more hardware processors in electronic communication with the optical sensor, the one or more hardware processors configured to:

[measure] *determine* oxygen saturation values of [a] *the* patient over a first period of time;

[determine if] *when* at least one oxygen saturation value obtained over the first period of time exceeds a first alarm threshold[;], determine whether a first alarm should be triggered [based on the determination that the at least one oxygen saturation value obtained over the first period of time exceeds the first alarm threshold];

[determine] *access* a second alarm threshold to be applied during a second period of time subsequent to the first period of time, the second alarm threshold replacing the first alarm threshold, *wherein* the second alarm threshold [being determined by:

comparing at least a first oxygen saturation value obtained during the first time period with a lower limit associated with oxygen saturation; and

computing a second alarm threshold based on the comparison where the second alarm threshold is computed to be at] *has* a value less than the at least [first] *one* oxygen saturation value and greater than [the] *a* lower limit and at an offset from the [first] *at least one* oxygen saturation value, wherein the offset [is configured to diminish] *is diminished* as a difference between the at least first oxygen saturation value and the lower limit diminishes;

[measure] *determine* oxygen saturation values of [a] *the* patient over the second period of time [to determine at least a second oxygen saturation value]; and

[determine whether] *trigger* a second alarm [should be triggered by determining if] *based on* at least one *value of the* oxygen saturation [value] *values* obtained [during] *over* the second period of time [exceeds] *exceeding* the second alarm threshold [and triggering an alarm if it is determined the second alarm should be triggered].

2. The system of claim **1**, wherein the one or more hardware processors are configured to calculate a first baseline measurement from the [measured] oxygen saturation values over the first period of time and wherein the at least one [oxygen saturation] value obtained during the first period of time corresponds to the first baseline measurement.

3. The system of claim **2**, wherein the one or more hardware processors are configured to calculate a second baseline measurement from the [measured] oxygen saturation values over the second period of time and wherein the at least one [oxygen saturation] value obtained during the second period of time corresponds to the second baseline measurement.

4. The system of claim **1**, wherein the lower limit is [predefined] *predetermined* and corresponds to a minimum parameter value for oxygen saturation.

5. The system of claim **1**, wherein the one or more hardware processors are further configured to wait for a time delay prior to the triggering of the second alarm, and wherein the time delay is a function of the second alarm threshold.

6. The system of claim **5**, wherein the time delay decreases as the difference between the at least [first oxygen saturation] *one* value and the lower limit diminishes.

7. The system of claim **1**, wherein the first alarm threshold is predetermined.

8. A system for reducing electronic alarms in a medical patient monitoring system including a pulse oximeter in communication with an optical sensor, the system comprising one or more hardware processors configured to:

[measure] *determine* oxygen saturation values of a patient over a first period of time;

determine if at least one oxygen saturation value obtained over the first period of time exceeds a first alarm threshold;

[determine whether a first alarm should be triggered based on the determination that the at least one oxygen saturation value obtained over the first period of time exceeds the first alarm threshold;

compare at least a first oxygen saturation value obtained during the first time period with a lower limit associated with oxygen saturation;

compute] *access* a second alarm threshold [based on the comparison];

[determine] *apply* a time delay based on the [computed] second alarm threshold, wherein the time delay approaches zero as the [first] *at least one* oxygen saturation value *obtained over the first period of time* approaches the lower limit;

[measure] *determine* oxygen saturation values of [a] *the* patient over [the] *a* second period of time [to determine at least a second oxygen saturation value] *different from the first period*; and

[determine whether] *trigger* a second alarm [should be triggered by determining if] *based on the* at least one oxygen saturation value obtained during the second period of time [exceeds] *exceeding* the second alarm threshold [for the time delay and triggering an alarm if it is determined the second alarm should be triggered], *where the second alarm threshold is at a value less than the at least one oxygen saturation value and greater than the lower limit and at an offset from the at least one oxygen saturation value, wherein the offset is diminished as a difference between the at least one oxygen saturation value and the lower limit diminishes*.

9. The system of claim **8**, wherein the first alarm threshold is predetermined.

10. The system of claim **8**, wherein the lower limit is [predefined] *predetermined* and corresponds to a minimum parameter value for oxygen saturation.

[**11**. The system of claim **8**, where the second alarm threshold is computed to be at a value less than the at least first oxygen saturation value and greater than the lower limit and at an offset from the first oxygen saturation value, wherein the offset is configured to diminish as a difference between the at least first oxygen saturation value and the lower limit diminishes.]

12. An electronic method [for] *of* reducing electronic alarms in a medical patient monitoring system, the electronic method comprising:

measuring*, with a pulse oximeter including a light source, an optical detector and one or more hardware processors configured to receive signals responsive to light attenuated by tissue of a patient,* oxygen saturation values of [a] *the* patient over a first period of time;

determining*, using the one or more hardware processors,* if at least one oxygen saturation value [determined] *measured* over the first period of time exceeds a first alarm threshold;

[determining whether a first alarm should be triggered based on the determination that at least one oxygen saturation value obtained during the first period of time exceeds the first alarm threshold;

comparing at least a first oxygen saturation value obtained during the first time period with a lower limit associated with oxygen saturation;

computing the] *applying, using the one or more hardware processors, a* second alarm threshold [based on the comparison where the second alarm threshold is computed to be] at a value (*i*) less than [the at least first] *an* oxygen saturation value [and] *of the patient,* (*ii*) greater than [the] *a* lower limit*,* (*iii*) and at an offset from the [first] oxygen saturation value *of the patient*, wherein the offset [is configured to diminish] *is diminished* as a difference between the [at least first] oxygen saturation value and the lower limit diminishes and wherein [the second alarm threshold is configured to be applied during a second period of time subsequent to the first period of time,] the second alarm threshold [replacing] *replaces* the first alarm threshold;

measuring*, using the pulse oximeter,* oxygen saturation values of [a] *the* patient over the second period of time to determine at least a second oxygen saturation value; and

determining*, using the one or more hardware processors,* whether *to trigger* a second alarm [should be triggered] by *at least* determining if at least one oxygen saturation value obtained during the second period of time exceeds the second alarm threshold [and triggering an alarm if it is determined the second alarm should be triggered].

13. The electronic method of claim **12**, wherein [the one or more hardware processors are configured to calculate] *the electronic method further comprises, using the one or more hardware processors, calculating* a first baseline measurement from the measured oxygen saturation values over the first period of time and wherein the at least one oxygen saturation value obtained during the first period of time corresponds to the first baseline measurement.

14. The electronic method of claim **13**, wherein [the one or more hardware processors are configured to calculate] *the electronic method further comprises, using the one or more hardware processors, calculating* a second baseline measurement from the measured oxygen saturation values over the second period of time and wherein the at least one oxygen saturation value obtained during the second period of time corresponds to the second baseline measurement.

15. The electronic method of claim **12**, wherein the lower limit is [predefined] *predetermined* and corresponds to a minimum parameter value for oxygen saturation.

16. The electronic method of claim **12**, wherein [the one or more hardware processors are further configured to wait] *the electronic method further comprises, using the one or more hardware processors, waiting* for a time delay prior to the triggering of the second alarm, and wherein the time delay is a function of the second alarm threshold.

17. The electronic method of claim **16**, wherein the time delay decreases as the difference between the at least [first] *one* oxygen saturation value and the lower limit diminishes.

18. The electronic method of claim **12**, wherein the first alarm threshold is predetermined.

* * * * *

US00RE47244E

(19) **United States**
(12) **Reissued Patent**
Kiani et al.

(10) **Patent Number: US RE47,244 E**
(45) **Date of Reissued Patent: Feb. 19, 2019**

(54) **ALARM SUSPEND SYSTEM**

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(21) Appl. No.: **15/583,935**

(22) Filed: **May 1, 2017**

Related U.S. Patent Documents

Reissue of:
(64) Patent No.: **9,153,121**
Issued: **Oct. 6, 2015**
Appl. No.: **14/469,426**
Filed: **Aug. 26, 2014**

U.S. Applications:
(63) Continuation of application No. 14/036,496, filed on Sep. 25, 2013, now Pat. No. 8,847,740, which is a
(Continued)

(51) **Int. Cl.**
G08B 5/22 (2006.01)
G08B 25/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/1455*** (2013.01); ***A61B 5/6826*** (2013.01); ***A61B 5/6838*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC ... A61B 5/1455; A61B 5/6826; A61B 5/6838; A61B 5/746; A61B 256/0276; G08B 25/001; G08B 5/22
(Continued)

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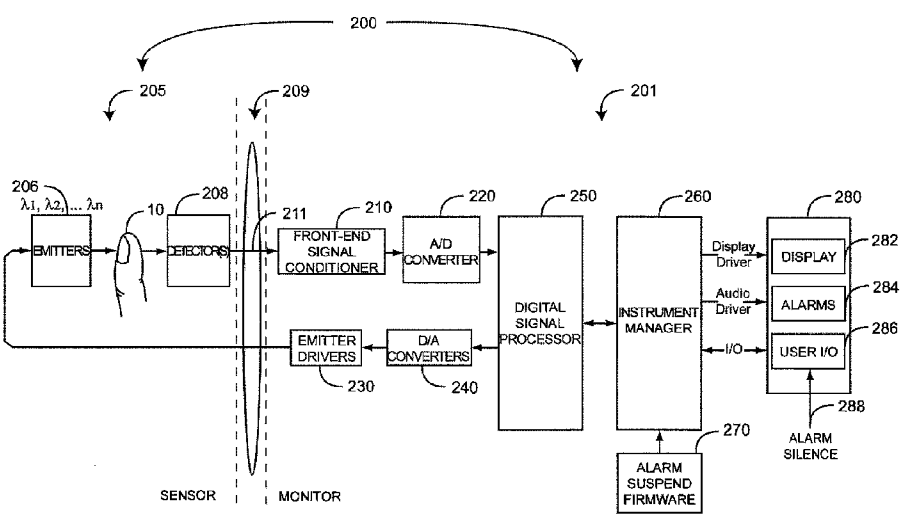
(57) **ABSTRACT**

An alarm suspend system utilizes an alarm trigger responsive to physiological parameters and corresponding limits on those parameters. The parameters are associated with both fast and slow treatment times corresponding to length of time it takes for a person to respond to medical treatment for out-of-limit parameter measurements. Audible and visual alarms respond to the alarm trigger. An alarm silence button is pressed to silence the audible alarm for a predetermined suspend time. The audible alarm is activated after the suspend time has lapsed. Longer suspend times are associated with slow treatment parameters and shorter suspend times are associated with fast treatment parameters.

26 Claims, 5 Drawing Sheets



Related U.S. Application Data

continuation of application No. 13/476,725, filed on May 21, 2012, now Pat. No. 8,547,209, which is a continuation of application No. 12/510,982, filed on Jul. 28, 2009, now Pat. No. 8,203,438.

(60) Provisional application No. 61/084,615, filed on Jul. 29, 2008.

(51) **Int. Cl.**
A61B 5/00 (2006.01)
A61B 5/1455 (2006.01)
G08B 25/01 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 5/746*** (2013.01); ***G08B 25/01*** (2013.01); *A61B 2560/0276* (2013.01); *G08B 5/22* (2013.01)

(58) **Field of Classification Search**
USPC .. 340/511, 517, 573.1, 539.12, 286.07, 527; 600/310, 316, 322–324, 336, 344, 507, 600/301, 320
See application file for complete search history.

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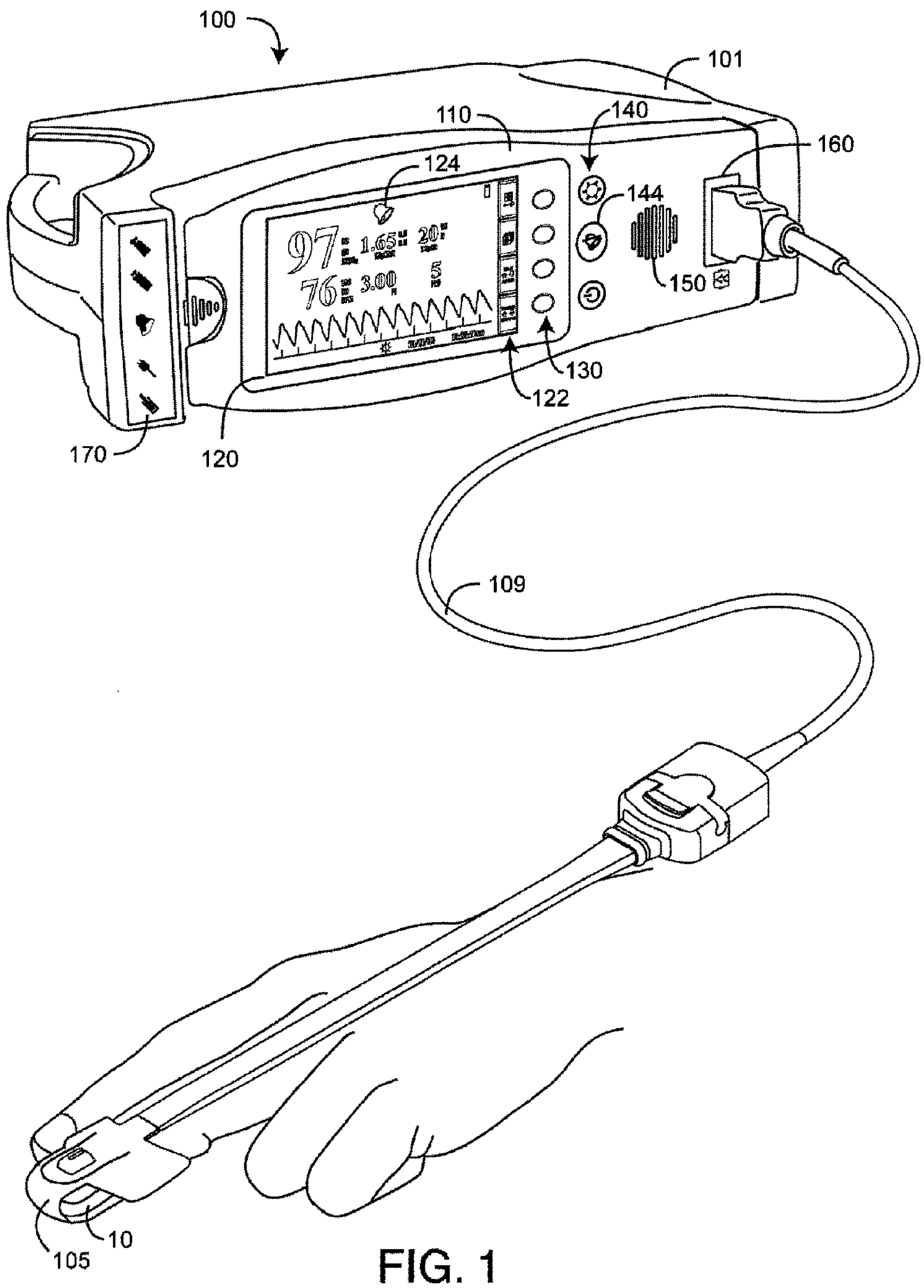
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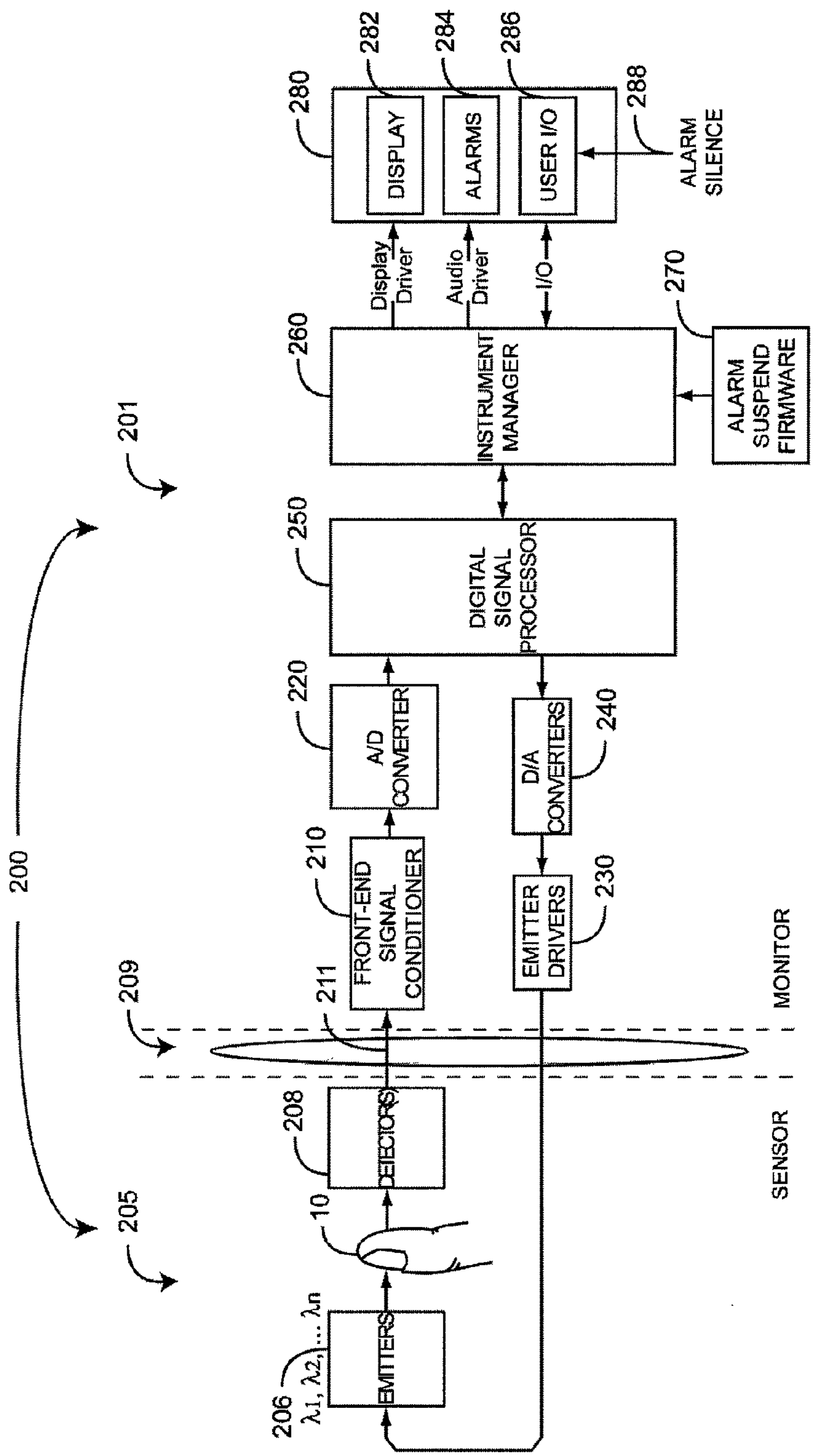
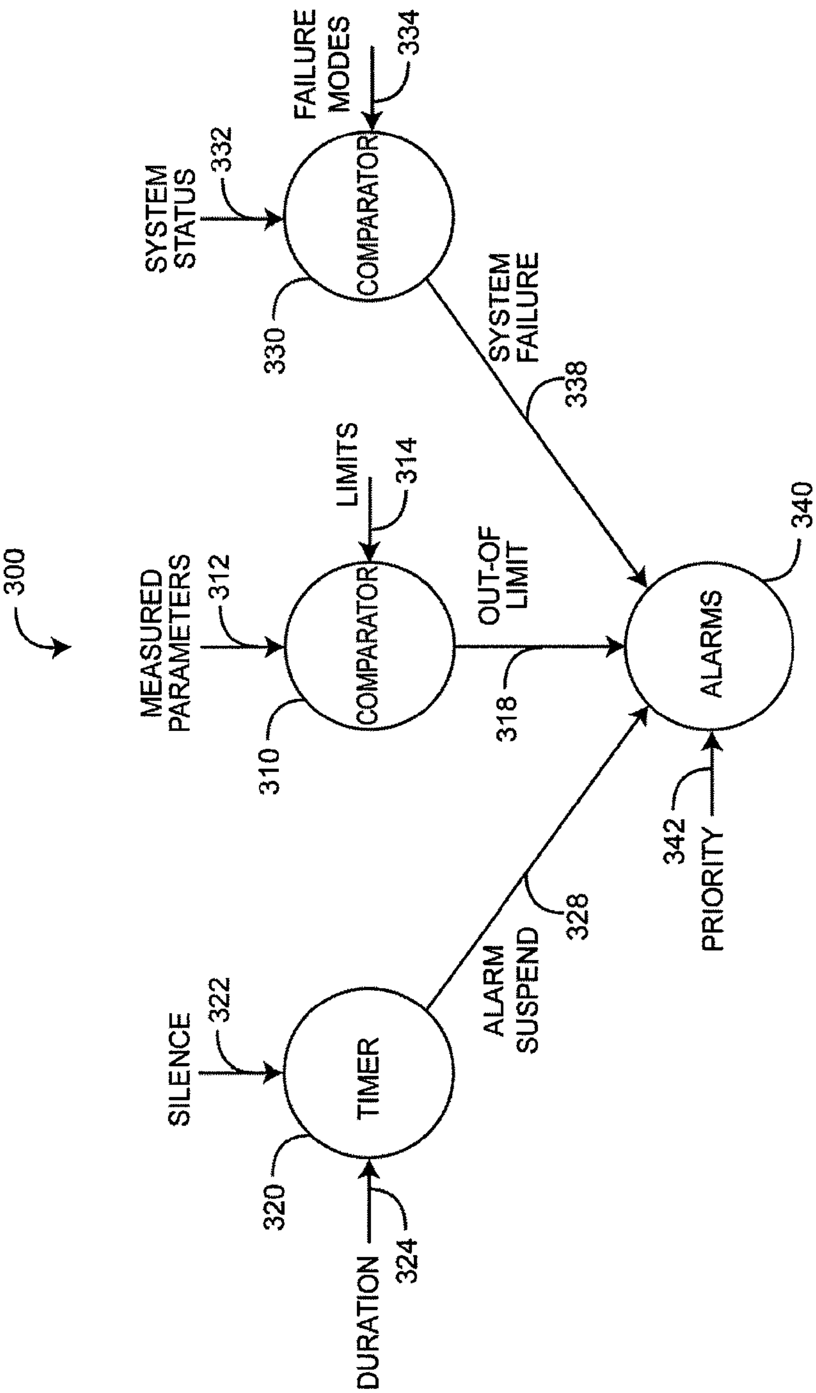
105

FIG. 1



200
201
205
209
206
$\lambda_1, \lambda_2, \ldots \lambda_n$
EMITTERS
10
208
DETECTOR(S)
SENSOR
211
MONITOR
210
FRONT-END SIGNAL CONDITIONER
220
A/D CONVERTER
230
EMITTER DRIVERS
240
D/A CONVERTERS
250
DIGITAL SIGNAL PROCESSOR
260
INSTRUMENT MANAGER
270
ALARM SUSPEND FIRMWARE
Display Driver
Audio Driver
I/O
280
DISPLAY
282
ALARMS
284
USER I/O
286
288
ALARM SILENCE

FIG. 2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334
SYSTEM FAILURE
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SILENCE
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TIMER
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DURATION
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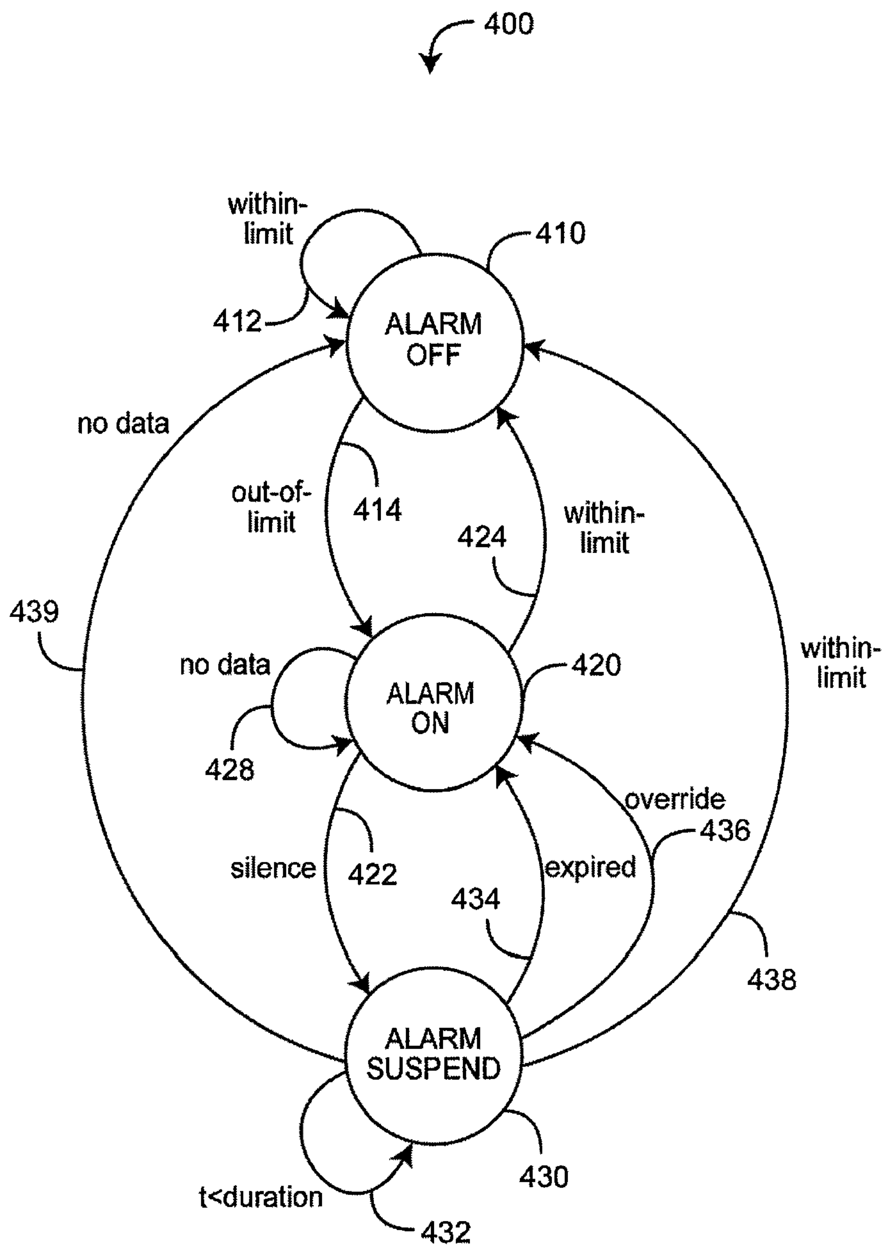
ALARM SUSPEND
328
ALARMS
340
PRIORITY
342

FIG. 3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limit
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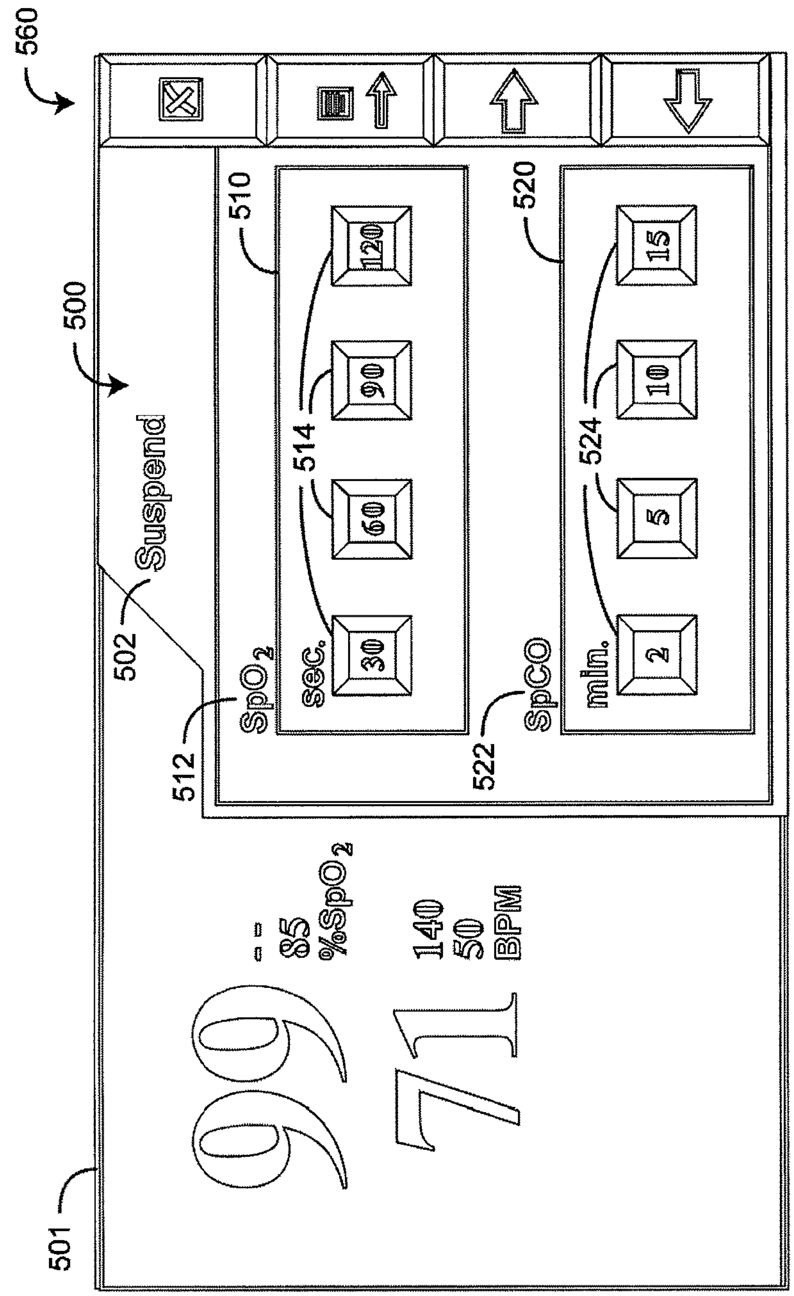
ALARM
ON
within-
limit
428
override
436
silence
422
expired
434
438
ALARM
SUSPEND
430
t<duration
432

FIG. 4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501
502
Suspend
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SpO2
sec.
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60
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514
520
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SpCO
min.
2
5
10
15
524
99
85
%SpO2
71
140
50
BPM

FIG. 5

ALARM SUSPEND SYSTEM

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

CROSS-REFERENCE TO RELATED APPLICATIONS

This [application] is *an application for reissue of U.S. Pat. No. 9,153,121, issued on Oct. 6, 2015 and titled "Alarm Suspend System," which is* a continuation of U.S. patent application Ser. No. 14/036,496, filed Sep. 25, 2013 and titled "Alarm Suspend System," which is a continuation of U.S. patent application Ser. No. 13/476,725, filed May 21, 2012 and titled "Alarm Suspend System," which is a continuation of U.S. patent application Ser. No. 12/510,982 filed Jul. 28, 2009 and titled "Alarm Suspend System," which claims priority benefit under 35 U.S.C. §119(e) to U.S. Provisional Patent Application Ser. No. 61/084,615, filed Jul. 29, 2008, titled "Alarm Management System[.]*;" more than one reissue application has been filed for the reissue of U.S. Pat. No. 9,153,121, including U.S. patent application Ser. No. 15/583,935 (the present application), U.S. patent application Ser. No. 15/583,922, and U.S. patent application Ser. No. 15/583,948.* All of the above-referenced applications are hereby incorporated by reference herein in their entireties.

BACKGROUND

Pulse oximetry for measuring constituents of circulating blood has achieved acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios. A pulse oximeter generally includes a two-wavelength optical sensor applied to a patient, a monitor for processing sensor signals and displaying results and a patient cable electrically interconnecting the sensor and the monitor. The monitor typically provides a numerical readout of physiological parameters such as oxygen saturation (SpO_2) and pulse rate (PR). Advanced physiological monitors utilize multiple wavelength sensors and enhanced measurement capabilities to provide readouts of additional parameters, such as carboxyhemoglobin (HbCO), methemoglobin (HbMet) and total hemoglobin (Hbt).

Pulse oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,650,917, 6,157,850, 6,002,952, 5,769,785 and 5,758,644; low noise pulse oximetry sensors are disclosed in at least U.S. Pat. Nos. 6,088,607 and 5,782,757; all of which are assigned to Masimo Corporation, Irvine, Calif. ("Masimo") and are incorporated by reference herein.

Physiological monitors and corresponding multiple wavelength optical sensors are described in at least U.S. patent application Ser. No. 11/367,013, filed Mar. 1, 2006 and titled Multiple Wavelength Sensor Emitters and U.S. patent application Ser. No. 11/366,208, filed Mar. 1, 2006 and titled Noninvasive Multi-Parameter Patient Monitor, both assigned to Masimo Laboratories, Irvine, Calif. (Masimo Labs) and both incorporated by reference herein.

Further, physiological monitoring systems that include low noise optical sensors and pulse oximetry monitors, such as any of LNOP® adhesive or reusable sensors, SofTouch™ sensors, Hi-Fi Trauma™ or Blue™ sensors; and any of Radical®, SatShare™, Rad-9™, Rad-5™, Rad-5v™ or PPO+™ Masimo SET® pulse oximeters, are all available from Masimo. Physiological monitoring systems including multiple wavelength sensors and corresponding noninvasive blood parameter monitors, such as Rainbow™ adhesive and reusable sensors and RAD-57™ and Radical-7™ monitors for measuring SpO_2, pulse rate (PR), perfusion index (PI), pleth variability index (PVI), signal quality, HbCO and HbMet among other parameters are also available from Masimo.

SUMMARY OF THE INVENTION

Monitor alarms are triggered by out-of-limit parameters and system failures, the latter including monitor or sensor failures or improper sensor placement, to name a few. Alarms can be visual, audible or both. Alarms can also have different levels of priority, which are reflected in the type of visual and audible alarms. In an embodiment, parameters exceeding limits such as low SpO_2, high HbCO, high HbMet and low and high BPM trigger high priority alarms. System failures due to sensor off, no sensor or defective sensor also trigger high priority alarms. Parameters exceeding limits such as high SpO_2, low and high PI, low and high PVI, for example, trigger medium priority alarms. Parameters exceeding limits such as low HbCO and low HbMet along with a system low battery indication are examples of low priority alarms.

An audible alarm may be temporarily suspended by pressing an alarm silence button so as to prevent unnecessary disturbance to the patient and distraction of the caregiver. During alarm suspension, visual alarms remain active. If an alarm condition persists after a predetermined alarm suspend period, the audible alarm resumes. The alarm suspend period is typically long enough to give a caregiver sufficient time to intervene with appropriate patient treatment yet short enough to ensure that patient health is not endangered if intervention is ineffective. For conventional pulse oximetry, an alarm suspend may be, for example, a maximum of 120 seconds.

Alarm suspension on advanced blood parameter monitors is problematic. With conventional pulse oximetry, treatment for abnormal parameter measurements can be quickly applied and a patient response is typically fast. For example, a treatment for low oxygen saturation is the application of an oxygen mask or an increase in oxygen flow. By contrast, the duration of treatment for parameters measured by advanced monitors is highly dependent on the alarm-triggering parameter. For example, the treatment for high methemoglobin is the injection of methylene blue, and the patient response to such an injection is slow. When patient treatment time exceeds the maximum alarm suspend period, an audible alarm will constantly reactivate. Thus, a single alarm suspend duration for all parameters is inadequate to cope with the many different types of parameters measured by advanced monitors.

One aspect of an alarm suspend system for silencing the alarms is an alarm trigger responsive to any of various parameters and predetermined limits corresponding to the parameters, where the parameters are partitioned according to treatment time, i.e. the relative length of time it takes for a person to respond to medical treatment for a parameter measurement outside of the predetermined limits. An

audible alarm is responsive to the alarm trigger. An alarm silence button is actuated so as to suspend the audible alarm. A timer tracks the duration of the suspended alarm and is initiated by actuation of an alarm silence button. The timer retriggers the audible alarm after the timed duration has lapsed/expired. In an embodiment, a long duration suspend time is associated with slow treatment parameters and a short duration suspend time is associated with fast treatment parameters. Fast treatment parameters may include, for example, parameters relating to normal blood hemoglobin constituents and slow treatment parameters may include parameters relating to abnormal blood hemoglobin constituents.

In various embodiments, a short duration suspend time is less than or equal to about two minutes and a long duration suspended time is greater than about two minutes. A default duration associated with the fast treatment parameters is about two minutes and a default duration associated with the slow treatment parameters is about fifteen minutes. The alarm suspend system may also have an alarm suspend override responsive to a predetermined unit change in the parameter triggering a suspended alarm. The override results in reactivation of the suspended alarm. A physiological monitor having an alarm suspend system may also have a pop-up window that appears on the monitor display in response to actuation of the silence button, where the pop-up window presents a choice of alarm suspend durations.

Another aspect of an alarm suspend system is a partition of measured parameters into at least a first group and a second group. An audible alarm is triggered if at least one parameter is outside of predetermined limits. The audible alarm is suspended in response to a silence request. A first duration is associated with the first group and a second duration is associated with the second group. The audible alarm is reactivated after at least one of the first duration and the second duration. The first duration may be set so as to generally correspond to a first range of treatment times for the first group of parameters. Likewise, the second duration may be set so as to generally correspond to a second range of treatment times for the second group of parameters, where the first range of treatment times and the second range of treatment times are non-overlapping.

In various embodiments, suspended audible alarms are overridden if the triggering parameter has greater than a predetermined unit change before the suspended alarm expires according to either the first duration or the second duration. The first and second groups are defined in relation to normal hemoglobin measurements abnormal hemoglobin measurements, respectively. The first duration is set to be less than or equal to two minutes and the second duration is set to be greater than two minutes, with default durations of about two minutes corresponding to the first group and about fifteen minutes corresponding to the second group. In an embodiment, a pop-up window for a monitor display is constructed and the first duration and the second duration are selected from a range of durations presented within the pop-up window.

A further aspect of an alarm suspend system deactivates an audible alarm for one of a short duration and a long duration according to the alarm-triggering parameter. A first group of parameters is associated with the short duration and a second group of parameters is associated with the long duration. The first group and the second group are partitioned according to a fast treatment time and a short treatment time associated with the parameters. An override reactivates the audible alarm if the trigger parameter changes more than a predetermine amount during the corresponding duration. In various embodiments, the first group comprises parameters related to the measurement of normal hemoglobin and the second group comprises parameters related to the measurement of abnormal hemoglobin. The long duration is greater than about 120 seconds and the short duration is less than or equal to about 120 seconds. A pop-up window for the display allows selection of the long duration and the short duration in response to the silence button.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a physiological measurement system utilizing an alarm suspend system;

FIG. **2** is a detailed block diagram of a physiological measurement system utilizing an alarm suspend system;

FIG. **3** is a flow diagram of an alarm suspend system embodiment;

FIG. **4** is a state diagram of an alarm suspend system embodiment; and

FIG. **5** is an illustration of an alarm suspend pop-up window.

DETAILED DESCRIPTION

FIG. **1** illustrates a physiological measurement system **100** that utilizes an alarm suspend system. The physiological measurement system **100** has a noninvasive sensor **105** attached to a tissue site **10**, a physiological monitor **101**, and an interface cable **109** interconnecting the monitor **101** and the sensor **105**. The physiological measurement system **100** may incorporate pulse oximetry in addition to advanced features, such as a multiple wavelength sensor and advanced processes for determining physiological parameters other than or in addition to those of pulse oximetry, such as carboxyhemoglobin, methemoglobin and total hemoglobin, as a few examples.

The monitor **101** has a front panel **110** providing a display **120**, touch keys **130**, controls **140**, a speaker **150**, a sensor port **160** and status indicators **170**. The display **120** shows parameter readouts, limits and waveforms among other items. The display **120** also has touch key icons **122** that indicate touch key **130** functions. The speaker **150** provides an audible alarm in response to physiological measurements that violate preset conditions, such as an out-of-limit parameter, as well as system failures, such as a low battery condition. The controls **140** include an alarm silence button **144** that is pressed to temporarily suspend out-of-limit parameter alarms and system alarms, such as low battery. The display **120** provides visual alarms, which include a bell-shaped alarm status indicator **124** that illuminates during an alarm condition and parameter readouts **210** and limits **220** that flash when parameters are out-of-limit. Status indicators **170** also provide visual alarms. When there are multiple alarm conditions, the parameter displays **202** indicate parameters with the highest alarm priority. Touch keys **130** and corresponding icons **122** include an alarm menu access button for setting alarm conditions, such as high or low alarm limits for SpO_2, HbCO, HbMet, PR and PI. The alarm silence button **144** is pressed to temporarily suspend audible alarms. Advantageously, an alarm suspend system provides a parameter-dependent variation in the alarm suspend duration, as described below, utilizing a common silence button or other suspend initiator.

FIG. **2** illustrates a physiological measurement system **200** including a physiological monitor **201**, a sensor **205** and an interface cable **209**. The sensor **205** is attached to a tissue site, such as a finger **10**, and includes a plurality of emitters

206 irradiating the tissue site **10** with multiple wavelengths of light. The sensor **205** also includes one or more detectors **208** capable of detecting the light after attenuation by the tissue site **10**. The sensor **205** transmits optical radiation at wavelengths other than or including the red and infrared wavelengths utilized in pulse oximeters. The monitor **201** inputs a corresponding sensor signal **211** and determines the relative concentrations of blood constituents other than or in addition to the "normal" blood hemoglobin constituents HbO_2 and Hb, including "abnormal" blood hemoglobin constituents HbCO, HbMet and blood related parameters such as fractional oxygen saturation, total hemoglobin and blood glucose to name a few.

As shown in FIG. **2**, the monitor **201** has a front-end signal conditioner **210**, an A/D converter **220**, emitter drivers **230**, D/A converters **240** and a digital signal processor ("DSP") **250**. In general, the emitter drivers **230** convert digital control signals, via the D/A converters **240**, into analog drive signals capable of driving the sensor emitters **206**. The front-end signal conditioner **210** converts, via the A/D converter **220**, composite analog intensity signal(s) from light sensitive detector(s) **208** into digital data input to the DSP **250**. The emitter drivers **230** and front-end signal conditioner **210** communicate with the sensor **205** via the interface cable **209**.

Also shown in FIG. **2**, the monitor **201** has an instrument manager **260** and a user interface **280**. The user interface **280** includes one or more displays **282**, alarms **284** and user input/output (I/O) **286**. The instrument manager **260** communicates with the DSP **250** to receive parameter data and to present that data on the display **282**. The instrument manager **260** may also store and display historical or trending data related to one or more of the measured parameters or combinations of the measured parameters. The instrument manager **260** also controls audible and visual alarms and indicators **284**. The instrument manager **260** responds to user-actuated keys and communicates with external devices via various I/O ports **286**. Further, the instrument manager **260** executes alarm suspend firmware **270** so as to respond to an alarm silence button press **288**, as described in detail with respect to FIGS. **3**-**4**.

FIG. **3** generally illustrates an alarm suspend system **300**. Alarm triggers include system failures **338** and out-of-limit parameters **318**. Triggered alarms **340** may be audible, visual or both, and may vary according to priority **342**. Audible alarms may be generated by a monitor front-panel-mounted speaker **150** (FIG. **1**) and may vary in loudness, pitch and sound pattern. Visual alarms may include parameter labels, parameter numerics, symbols and status lights, which can flash and vary in color.

As shown in FIG. **3**, measured parameters **312** are compared **310** to default or user-specified limits **314**. An out-of-limit condition **318** triggers an alarm **340**. An alarm suspend **328** is user-initiated by a silence request **322**. This may be a press of a silence button **144** (FIG. **1**) on a monitor front panel **110** (FIG. **1**). In an embodiment, the alarm suspend **328** silences audible alarms and modifies the display of visual alarms. The alarm suspend **328** is based on a timer **320**, which ends the alarm suspend **328** after a predetermined duration **324**. The duration **324** may be a function of the out-of-limit parameter **312**. In an advantageous embodiment, the duration **324** relates to, or is a function of, the treatment time for the alarm-triggering parameter so as to avoid nuisance alarms while maintaining alarm integrity.

FIG. **4** illustrates an alarm suspend embodiment **400** that operates independently for each measured parameter that

can trigger an alarm. An alarm is initially off **410**. The alarm remains off as long as the parameter is within its set limits **412**. If a parameter is measured outside of its set limits **414**, an alarm is triggered **420**. The alarm may audible, visual or both audible and visual. A user can request to silence the alarm by pressing an alarm silence button **144** (FIG. **1**), for example. The silence request **422** suspends the alarm **430** which turns off audible alarms but, in an embodiment, does not deactivate visual alarms. The audible alarm remains suspended **430** for a predetermined duration **432**. When the suspend duration has passed, the alarm suspend expires **434** and audible alarms are once again activated **420**. The alarm remains on **428** until the triggering parameter is within limits **424** or a user once again requests silence **422**. The alarm suspend **430** deactivates if the measured parameter becomes within limits **438**, such as when the patient condition improves, or if no physiological data is detected **439**, such as no sensor, sensor off, no cable or malfunctioning sensor situations, to name a few. Also, if the measured parameter changes during the alarm suspend **430** by a sufficient out-of-limit amount, an override **436** reactivates the audible alarms **420**.

In an alarm suspend system embodiment, parameters are classified according to the typical time it takes for medical treatment to transition an out-of-limit measurement to a within-limit measurement. Suspend durations **324** (FIG. **3**) are set accordingly. For example, in a two-tier embodiment, relatively slow treatment parameters, such as HbMet, HbCO, Hbt and PVI, are assigned relatively long suspend durations. Similarly, relatively fast treatment parameters, such as SpO_2 and PR, are assigned relatively short suspend durations. In an embodiment, the alarm suspend duration is adjustable for each individual parameter, including 2, 5, 10, 15, 20, 25 and 30 minutes for slow treatment parameters, with a default of 15 minutes; and 30, 60, 90 and 120 seconds for fast treatment parameters, with a default of 120 seconds. These alarm features are only active when alarm limits have been set. Other alarm features apply to both slow treatment and fast treatment parameters. For example, an alarm delay of 0, 5, 10 or 15 seconds applies to all enabled parameters.

In an embodiment, an override **436** occurs if slow treatment parameters such as HbCO, HbMet or PVI increase or Hbt decreases by a certain unit change during the alarm suspend duration. The unit change is adjustable for each parameter, such as from 1-15 in increments of 1. TABLE 1 shows a default embodiment of override unit changes for these parameters.

TABLE 1

Override Unit Changes for Selected Parameters

Parameter	Unit Change	Direction
HbCO	5	Increase
HbMet	2	Increase
Hbt	2	Decrease
PVI	OFF	Increase

FIG. **5** illustrates an alarm suspend window **500** that provides a "pop-up" display so that a monitor user may manually enter an alarm suspend duration. The alarm suspend window **500** appears as a portion of a monitor display **501**, such as the front panel display **120** (FIG. **1**) described above. The pop-up window **500** responds to a suspend request, such as a silence button **144** (FIG. **1**) press. The alarm suspend window **500** has a window identifier **502** and one or more parameter subsections **510**, **520**. Each param-

eter subsection **510**, **520** has a parameter identifier **512**, **522** and corresponding suspend duration options **514**, **524**. In an embodiment, specific suspend times are selected via monitor touch keys **130** (FIG. **1**) as guided by corresponding touch key icons **560**. Selected suspend times are highlighted or otherwise identified and entered, also via a touch key **130** (FIG. **1**). In an alternative embodiment, the monitor display is a touch screen and alarm suspend times are directly entered by a finger press on a specific duration "virtual button" **514**, **524**. Once one or more suspend durations are entered, the pop-up window **500** disappears from the display **501**. The alarm suspend window **500** advantageously allows a user to quickly choose an appropriate alarm suspend duration for the situation at hand, rather than relying on a predetermined or default duration.

An alarm suspend system is described above with respect to alarms triggered by measured parameters and limits associated with those measured parameters. Limits may correspond to levels of a measured parameter, such as a percentage oxygen saturation to name but one example. Limits may also correspond to trends of a measured parameter, such as a rate-of-change of oxygen saturation, for example. Limits may also correspond to patterns in a measured parameter or a comparison of one measured parameter with another measured parameter, as further examples.

An alarm suspend system is described above with respect to a two-tier grouping of parameters, such as slow treatment and fast treatment parameters and alarm suspend durations associated with those groups. Groupings of parameters with respect to alarm suspend durations may be multi-tier, such as slow, medium and fast treatment parameters, to name but one example.

An alarm suspend system has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.

What is claimed is:

1. A physiological measurement system comprising:

a *noninvasive* physiological sensor [including: a plurality of light emitting diodes] configured to [transmit wavelengths of light onto a tissue site of a patient; and at least one detector configured to measure an indication of the wavelengths of light after attenuation by tissue of the patient and] *be positioned on a patient and* output a signal responsive [of the attenuated light] *to a physiological condition of the patient*; and

one or more processors in communication with the *noninvasive* physiological sensor, the one or more processors configured to *electronically*:

process the signal;

responsive to processing the signal, determine a measurement of a physiological parameter based at least in part upon the signal;

determine that the measurement of the physiological parameter satisfies an alarm activation threshold;

[receive, from a user, an indication of] *initiate* a parameter-specific alarm *delay or* suspension period of time corresponding to the physiological parameter, the parameter-specific alarm *delay or* suspension period of time being [selected from] *one of* a plurality of parameter-specific alarm *delay or* suspension periods of time, the parameter-specific alarm *delay or* suspension period of time being different from at least one other parameter-specific alarm *delay or* suspension period of time corresponding to at least one other physiological parameter *for which the one or more processors are configured to determine at least one measurement*; [activate an alarm in response to determining that an alarm activation threshold has been satisfied by the physiological parameter measurement; receive an alarm suspension indication;] and

[in response to receiving the alarm suspension indication, suspend the alarm for] *activate an alarm for the physiological parameter in response to expiration of an amount of delay or suspension associated with* the [indicated] parameter-specific alarm *delay or* suspension period of time.

2. The physiological measurement system of claim **1**, wherein the one or more processors are further configured to:

provide a user interface to the user including at least a plurality of user-selectable elements, each of the [selectable] *plurality of user-selectable* elements corresponding to one of the plurality of parameter-specific alarm *delay or* suspension periods of time.

3. The physiological measurement system of claim **2**, wherein providing the user interface further includes:

constructing a pop-up window for a display; and

displaying the plurality of user-selectable elements in the pop-up window.

4. The physiological measurement system of claim **3**, wherein the plurality of user-selectable elements are configured to allow a user to select a specific one of the plurality of parameter-specific alarm *delay or* suspension periods of time.

5. The physiological measurement system of claim **4**, wherein [the] *a* selected parameter-specific alarm *delay or* suspension period of time is selected by selection of one of the plurality of user-selectable elements.

6. The physiological measurement system of claim **1**, wherein the one or more processors are further configured to:

associate [the] *a* selected parameter-specific *alarm delay or suspension* period of time [is] with the physiological parameter.

7. The physiological measurement system of claim **6**, wherein the selected parameter-specific *alarm delay or suspension* period of time is stored in a memory device in communication with the one or more processors.

8. The physiological measurement system of claim **1**, wherein the one or more processors are further configured to:

responsive to processing the signal, determine a *measurement of a* second physiological parameter [measurement] based at least in part upon the signal;

determine that the measurement of the second physiological parameter satisfies a second alarm activation threshold;

[receive, from the user, a second indication of] *initiate* a second parameter-specific alarm *delay or* suspension period of time corresponding to the second physiological parameter, the second parameter-specific alarm *delay or* suspension period of time being [selected from] *one of* a second plurality of parameter-specific alarm *delay or* suspension periods of time; [activate a second alarm in response to determining a second alarm activation threshold has been satisfied by the second physiological parameter measurement;] and

[in response to receiving the alarm suspension indication, suspend the second alarm for] *activate a second alarm for the second physiological parameter in response to expiration of an amount of delay or suspension asso-*

ciated with the [indicated] second parameter-specific alarm *delay or* suspension period of time.

9. The physiological measurement system of claim **8**, wherein the one or more processors are further configured to:

provide a user interface to the user including at least a first plurality of user-selectable elements and a second plurality of user-selectable elements, wherein each of the first plurality of user-selectable elements corresponds to one of the plurality of parameter-specific alarm *delay or* suspension periods of time, and each of the second plurality of user-selectable element corresponds to one of the second plurality of parameter-specific alarm *delay or* suspension periods of time.

10. The physiological measurement system of claim **9**, wherein the one or more processors are further configured to:

construct a pop-up window for a display; and

display both the first and second plurality of user-selectable elements in the pop-up window.

11. The physiological measurement system of claim **10**, wherein [the] *a* selected parameter-specific alarm *delay or* suspension period of time is selected by selection of one of the first plurality of user-selectable elements, and [the] *a* selected second parameter-specific alarm *delay or* suspension period of time is selected by selection of one of the second plurality of user-selectable elements.

12. The physiological measurement system of claim **11**, wherein the at least one of the first plurality of parameter-specific alarm *delay or* suspension periods of time is different from any of the second plurality of parameter-specific alarm *delay or* suspension periods of time.

13. [An] *A* method *of electronically delaying or suspending an alarm while an electronically calculated measurement of a physiological parameter satisfies an alarm activation threshold, the measurement of the physiological parameter responsive to a signal from a noninvasive sensor positioned at a monitored patient, the method* comprising:

electronically processing a signal from a noninvasive sensor;

[measuring] *responsive to processing the signal, electronically determining a first measurement of* a *first* physiological parameter *and a second measurement of a second physiological parameter* using a patient monitoring device, the patient monitoring device including a processor and a memory device [configured to store]*;*

electronically storing, using the patient monitoring device, a *first* parameter-specific alarm *delay or* suspension period of time *corresponding to the first physiological parameter and a second parameter-specific alarm delay or suspension period of time corresponding to the second physiological parameter, the first parameter-specific alarm delay or suspension period of time being different from the second parameter-specific alarm delay or suspension period of time*;

electronically determining, using the patient monitoring device, that the first measurement of the first physiological parameter satisfies a first alarm activation threshold;

[receiving, from a user, an indication of a] *electronically initiating, using the patient monitoring device, the first* parameter-specific alarm *delay or* suspension period of time [corresponding to the physiological parameter, the parameter-specific alarm suspension period of time being selected from a plurality of parameter-specific alarm suspension periods of time, the parameter-specific alarm suspension period of time being different from at least one other parameter-specific alarm suspension period of time corresponding to at least one other physiological parameter; activating an alarm in response to determining an alarm activation threshold has been satisfied by the physiological parameter measurement; receiving an alarm suspension indication]; and

[in response to receiving the alarm suspension indication, suspending the alarm for] *electronically activating, using the patient monitoring device, a first alarm for the first physiological parameter in response to expiration of a first amount of delay or suspension associated with* the [indicated] *first* parameter-specific alarm *delay or* suspension period of time.

14. The method of claim **13**, wherein the *first* alarm includes an audible component and a visual component, and wherein [suspending] *activating* the *first* alarm *in response to expiration of the first amount of delay or suspension* comprises [suspending] *activating* the audible component [and not suspending the visual component].

15. The method of claim **13** further comprising:

providing a user interface to the user including at least a plurality of user-selectable elements, each of the [selectable] *plurality of user-selectable* elements corresponding to one of [the] *a* plurality of parameter-specific alarm *delay or* suspension periods of time*,*

wherein the plurality of parameter-specific alarm delay or suspension periods of time comprise the first parameter-specific alarm delay or suspension period of time.

16. The method of claim **15** further comprising:

constructing a pop-up window for a display; and

displaying the plurality of user-selectable elements in the pop-up window.

17. The method of claim **16**, wherein [the] *a* selected parameter-specific alarm *delay or* suspension period of time is selected by selection of one of the plurality of user-selectable elements.

18. A physiological measurement system comprising:

a physiological sensor means for outputting a signal responsive to a [noninvasive measurement of attenuated light transmitted through a tissue site] *physiological condition* of a patient;

a memory configured to store a first alarm activation threshold; and

[a processing means] *one or more processors* in communication with the physiological sensor means and configured to:

process the signal;

responsive to processing the signal, determine a *first* measurement of [a] *the first measured* physiological parameter based at least in part upon the signal;

[receive, from a user, an indication of] *initiate* a *first* parameter-specific alarm *delay or* suspension period of time corresponding to the *first measured* physiological parameter, [the parameter-specific alarm suspension period of time being selected from a plurality of parameter-specific alarm suspension periods of time,] the *first* parameter-specific alarm *delay or* suspension period of time being different from [at least one other] *a second* parameter-specific alarm *delay or* suspension period of time corresponding to [at least one other] *a second measured* physiological parameter *for which the one or more processors are configured to determine a second measurement*;

delay or suspend activation of an alarm for the first measured physiological parameter for the first

parameter-specific alarm delay or suspension period of time while the first alarm activation threshold is satisfied by the measurement of the first measured physiological parameter; and

subsequent to delaying or suspending activation of the alarm for the first parameter-specific alarm delay or suspension period of time, activate [an] *the* alarm in response to determining [an] *the first* alarm activation threshold [has been] *is* satisfied by the *first measurement of the first measured* physiological parameter [measurement; receive an alarm suspension indication; and in response to receiving the alarm suspension indication, suspend the alarm for the indicated parameter-specific alarm suspension period of time].

19. The physiological measurement system of claim **18**, wherein the [processing means is] *one or more processors are* further configured to:

responsive to processing the signal, determine [a] *the* second [physiological parameter] measurement based at least in part upon the signal;

[receive, from the user, a second indication of a] *initiate the* second parameter-specific alarm *delay or* suspension period of time [corresponding to the second physiological parameter, the second parameter-specific alarm suspension period of time being selected from a second plurality of parameter-specific alarm suspension periods of time];

delay or suspend activation of a second alarm for the second measured physiological parameter for the second parameter-specific alarm delay or suspension period of time while a second alarm activation threshold is satisfied by the second measurement; and

subsequent to delaying or suspending activation of the second alarm for the second parameter-specific alarm delay or suspension period of time, activate [a] *the* second alarm [in response] *responsive* to determining [a] *that the* second alarm activation threshold [has been] *is* satisfied by the second [physiological parameter] measurement[; and

in response to receiving the alarm suspension indication, suspend the second alarm for the indicated second parameter-specific alarm suspension period of time].

20. The physiological measurement system of claim **19**, wherein the [processing means is] *one or more processors are* further configured to:

provide a user interface to the user including at least a first plurality of user-selectable elements and a second plurality of user-selectable elements, wherein each of the first plurality of user-selectable elements corresponds to one of [the] *a first* plurality of parameter-specific alarm *delay or* suspension periods of time, and each of the second plurality of user-selectable element corresponds to one of [the] *a* second plurality of parameter-specific alarm *delay or* suspension periods of time*,*

wherein the first plurality of parameter-specific alarm delay or suspension periods of time comprise the first parameter-specific alarm delay or suspension period of time, and the second plurality of parameter-specific alarm delay or suspension periods of time comprise the second parameter-specific alarm delay or suspension period of time.

21. The physiological measurement system of claim **20**, wherein [the] *a* selected *first* parameter-specific alarm *delay or* suspension period of time is selected by selection of one of the first plurality of user-selectable elements, and [the] *a* selected second parameter-specific alarm *delay or* suspension period of time is selected by selection of one of the second plurality of user-selectable elements.

22. The physiological measurement system of claim **21**, wherein at least one of the first plurality of parameter-specific alarm *delay or* suspension periods of time is different from any of the second plurality of parameter-specific alarm *delay or* suspension periods of time.

23. The physiological measurement system of claim 1, wherein the alarm comprises an audible alarm.

24. The physiological measurement system of claim 1, wherein the one or more processors are further configured to:

determine that the measurement of the physiological parameter satisfies a second alarm activation threshold different from the alarm activation threshold; and

in response to determining that the measurement of the physiological parameter satisfies the second alarm activation threshold, activate the alarm for the physiological parameter prior to expiration of the amount of delay or suspension associated with the first parameter-specific alarm delay or suspension period of time.

25. The physiological measurement system of claim 1, wherein the one or more processors are further configured to:

determine that a measurement of a second physiological parameter satisfies a second alarm activation threshold; and

in response to determining the measurement of the second physiological parameter satisfies the second alarm activation threshold, activate an alarm for the second physiological parameter prior to expiration of the amount of delay or suspension associated with the first parameter-specific alarm delay or suspension period of time.

26. The physiological measurement system of claim 1, wherein the physiological parameter comprises an oxygen saturation, and the at least one other physiological parameter comprises a pulse rate.

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US00RE47249E

(19) **United States**
(12) **Reissued Patent**
Kiani et al.

(10) **Patent Number: US RE47,249 E**
(45) **Date of Reissued Patent: *Feb. 19, 2019**

(54) **ALARM SUSPEND SYSTEM**

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(*) Notice: This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/583,948**

(22) Filed: **May 1, 2017**

Related U.S. Patent Documents

Reissue of:
(64) Patent No.: **9,153,121**
Issued: **Oct. 6, 2015**
Appl. No.: **14/469,426**
Filed: **Aug. 26, 2014**

U.S. Applications:
(63) Continuation of application No. 14/036,496, filed on Sep. 25, 2013, now Pat. No. 8,847,740, which is a
(Continued)

(51) **Int. Cl.**
G08B 5/22 (2006.01)
A61B 5/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***G08B 25/001*** (2013.01); ***A61B 5/1455*** (2013.01); ***A61B 5/6826*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC ... A61B 5/1455; A61B 5/6826; A61B 5/6838; A61B 5/746; A61B 256/0276; G08B 25/001; G08B 5/22
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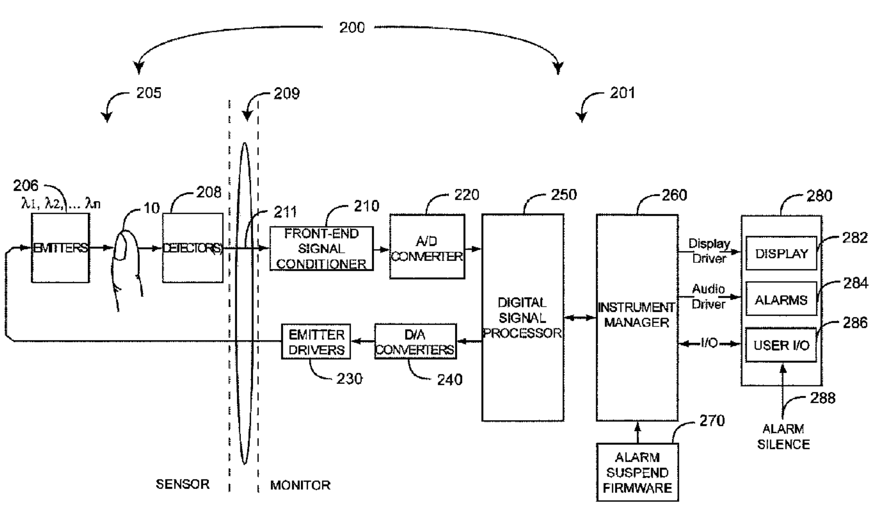
(57) **ABSTRACT**

An alarm suspend system utilizes an alarm trigger responsive to physiological parameters and corresponding limits on those parameters. The parameters are associated with both fast and slow treatment times corresponding to length of time it takes for a person to respond to medical treatment for out-of-limit parameter measurements. Audible and visual alarms respond to the alarm trigger. An alarm silence button is pressed to silence the audible alarm for a predetermined suspend time. The audible alarm is activated after the suspend time has lapsed. Longer suspend times are associated with slow treatment parameters and shorter suspend times are associated with fast treatment parameters.

24 Claims, 5 Drawing Sheets



Related U.S. Application Data

continuation of application No. 13/476,725, filed on May 21, 2012, now Pat. No. 8,547,209, which is a continuation of application No. 12/510,982, filed on Jul. 28, 2009, now Pat. No. 8,203,438.

(60) Provisional application No. 61/084,615, filed on Jul. 29, 2008.

(51) **Int. Cl.**
G08B 25/00 (2006.01)
A61B 5/1455 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 5/6838*** (2013.01); ***A61B 5/746*** (2013.01); *A61B 2560/0276* (2013.01); *G08B 5/22* (2013.01)

(58) **Field of Classification Search**
USPC .. 340/511, 517, 573.1, 539.12, 286.07, 527; 600/310, 316, 322–324, 336, 344, 507, 600/301, 320
See application file for complete search history.

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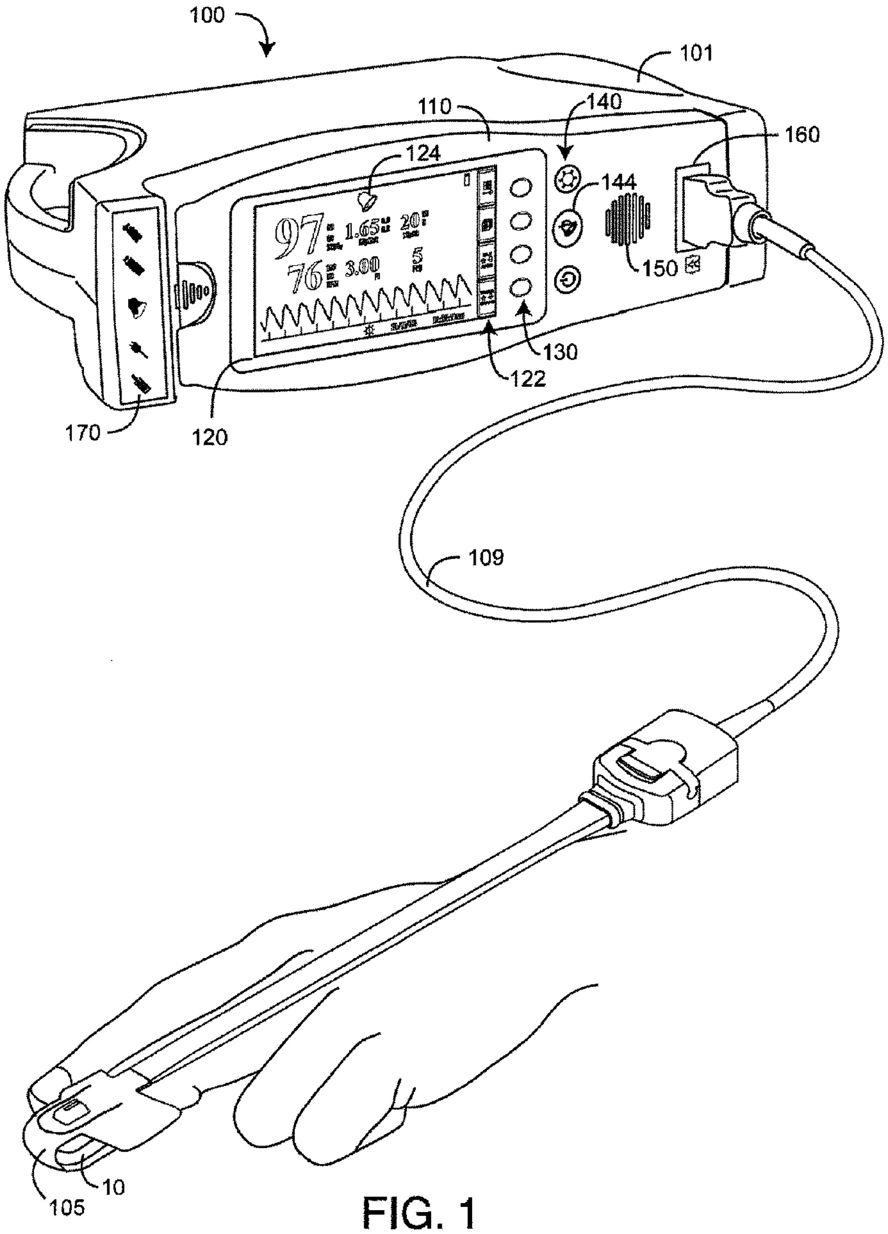

FIG. 1

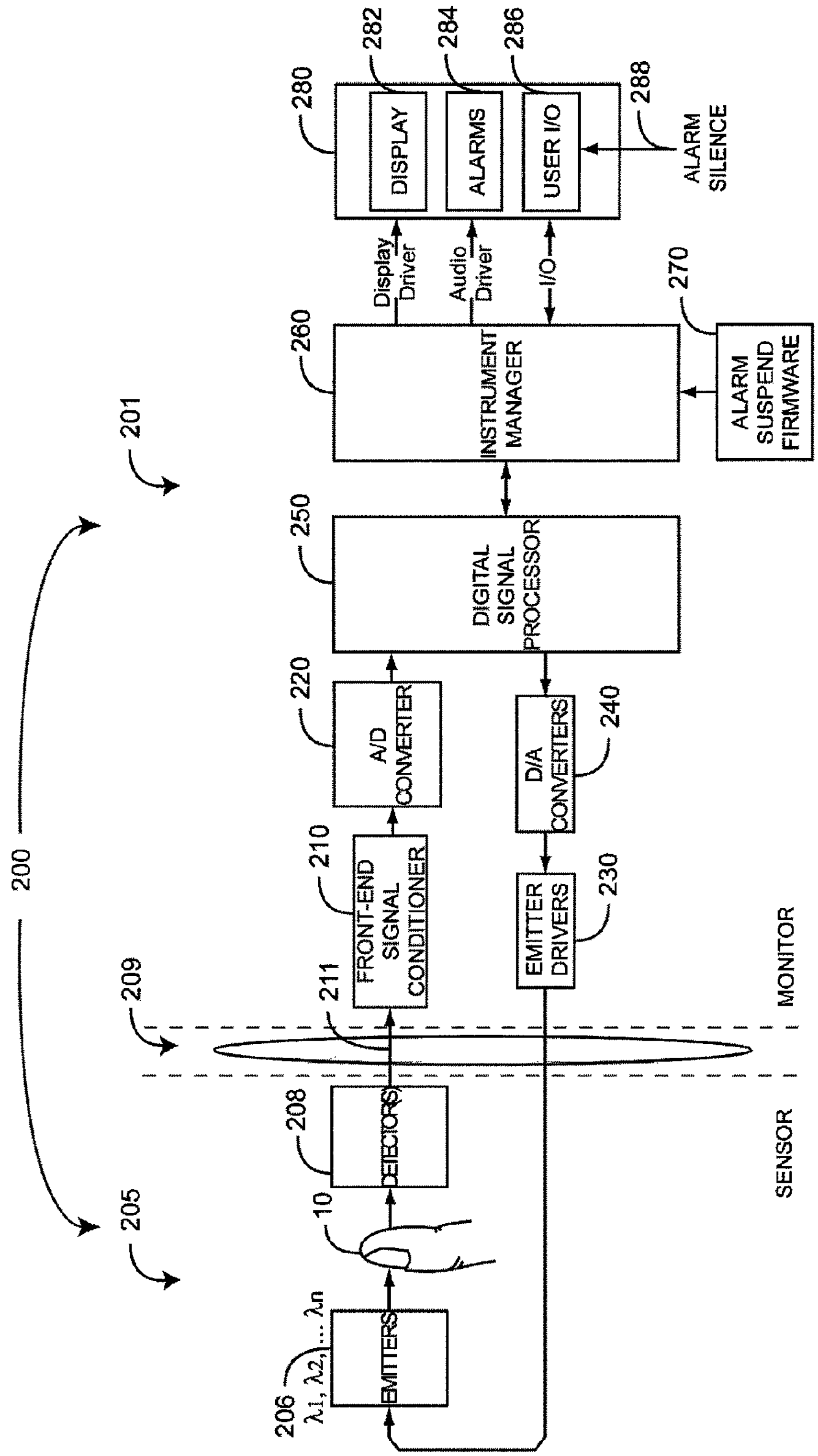
200
201
205
206
$\lambda_1, \lambda_2, \ldots \lambda_n$
EMITTERS
10
208
DETECTOR(S)
209
211
210
FRONT-END SIGNAL CONDITIONER
220
A/D CONVERTER
250
DIGITAL SIGNAL PROCESSOR
240
D/A CONVERTERS
230
EMITTER DRIVERS
260
INSTRUMENT MANAGER
270
ALARM SUSPEND FIRMWARE
Display Driver
Audio Driver
I/O
280
282
DISPLAY
284
ALARMS
286
USER I/O
288
ALARM SILENCE
SENSOR
MONITOR

FIG. 2

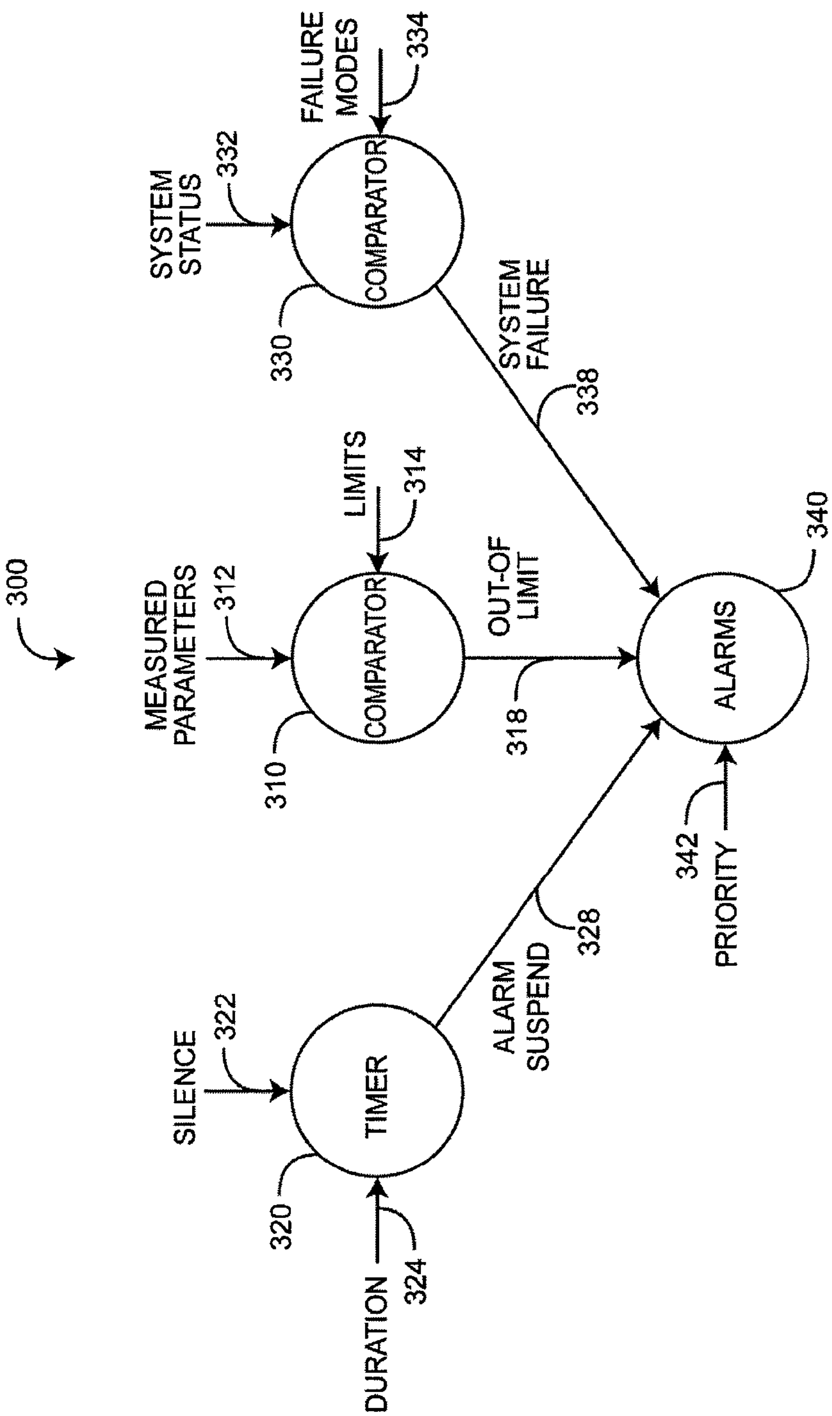
300
FAILURE MODES
334
SYSTEM STATUS
332
COMPARATOR
330
SYSTEM FAILURE
338
LIMITS
314
MEASURED PARAMETERS
312
COMPARATOR
310
OUT-OF LIMIT
318
ALARMS
340
PRIORITY
342
SILENCE
322
TIMER
320
DURATION
324
ALARM SUSPEND
328

FIG. 3

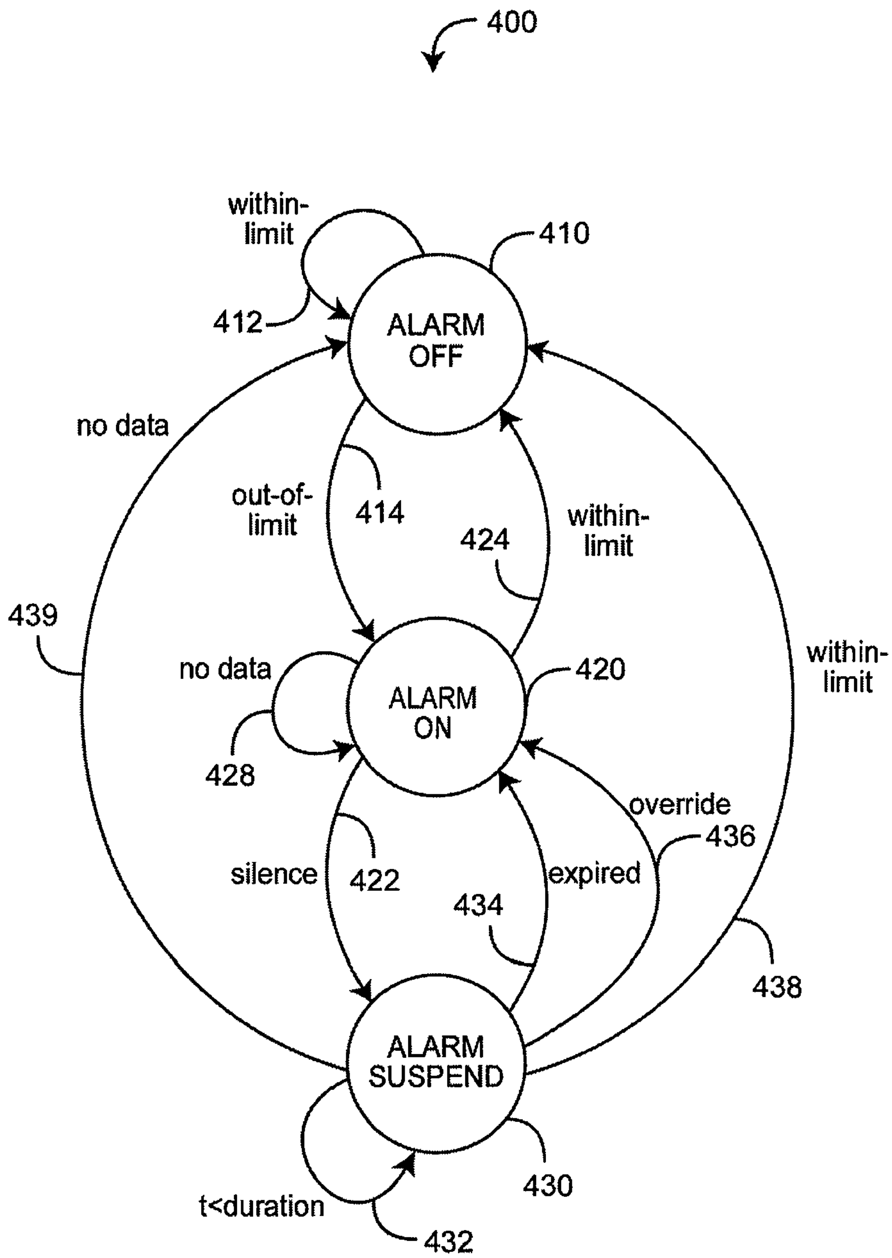
400
within-
limit
410
412
ALARM
OFF
no data
out-of-
limit
414
424
within-
limit
439
no data
ALARM
ON
420
within-
limit
428
override
436
silence
422
434
expired
438
ALARM
SUSPEND
t<duration
430
432

FIG. 4

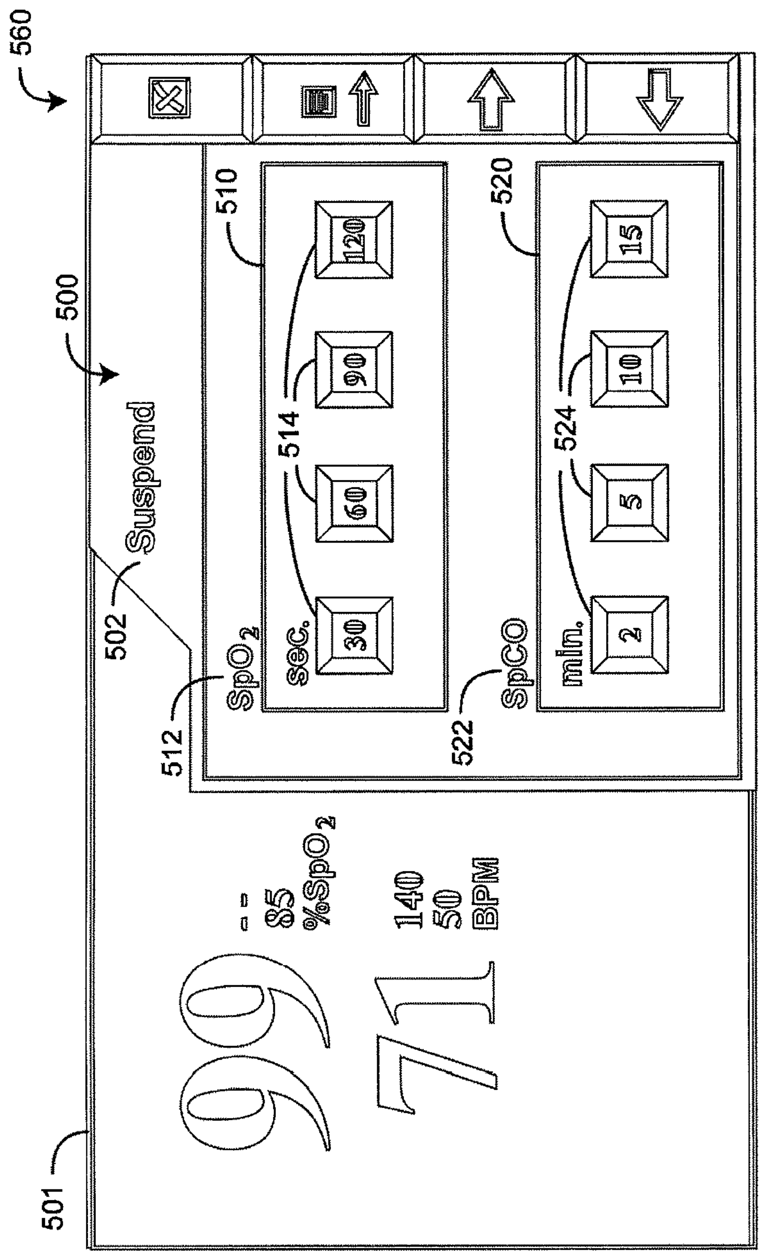
560
500
501
502
Suspend
510
512
514
520
522
524
SpO2
sec.
30
60
90
120
SpCO
min.
2
5
10
15
99
71
85
%SpO2
140
50
BPM

FIG. 5

ALARM SUSPEND SYSTEM

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

CROSS-REFERENCE TO RELATED APPLICATIONS

This [application] is *an application for reissue of U.S. Pat. No. 9,153,121, issued on Oct. 6, 2015 and titled "Alarm Suspend System," which is* a continuation of U.S. patent application Ser. No. 14/036,496, filed Sep. 25, 2013 and titled "Alarm Suspend System," which is a continuation of U.S. patent application Ser. No. 13/476,725, filed May 21, 2012 and titled "Alarm Suspend System," which is a continuation of U.S. patent application Ser. No. 12/510,982 filed Jul. 28, 2009 and titled "Alarm Suspend System," which claims priority benefit under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application Ser. No. 61/084,615, filed Jul. 29, 2008, titled "Alarm Management System*;" more than one reissue application has been filed for the reissue of U.S. Pat. No. 9,153,121, including U.S. patent application Ser. No. 15/583,948 (the present application), U.S. patent application Ser. No. 15/583,922, and U.S. patent application Ser. No. 15/583,935*.[."] All of the above-referenced applications are hereby incorporated by reference herein in their entireties.

BACKGROUND

Pulse oximetry for measuring constituents of circulating blood has achieved acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios. A pulse oximeter generally includes a two-wavelength optical sensor applied to a patient, a monitor for processing sensor signals and displaying results and a patient cable electrically interconnecting the sensor and the monitor. The monitor typically provides a numerical readout of physiological parameters such as oxygen saturation (SpO_2) and pulse rate (PR). Advanced physiological monitors utilize multiple wavelength sensors and enhanced measurement capabilities to provide readouts of additional parameters, such as carboxyhemoglobin (HbCO), methemoglobin (HbMet) and total hemoglobin (Hbt).

Pulse oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,650,917, 6,157,850, 6,002,952, 5,769,785 and 5,758,644; low noise pulse oximetry sensors are disclosed in at least U.S. Pat. Nos. 6,088,607 and 5,782,757; all of which are assigned to Masimo Corporation, Irvine, Calif. ("Masimo") and are incorporated by reference herein.

Physiological monitors and corresponding multiple wavelength optical sensors are described in at least U.S. patent application Ser. No. 11/367,013, filed Mar. 1, 2006 and titled Multiple Wavelength Sensor Emitters and U.S. patent application Ser. No. 11/366,208, filed Mar. 1, 2006 and titled Noninvasive Multi-Parameter Patient Monitor, both assigned to Masimo Laboratories, Irvine, Calif. (Masimo Labs) and both incorporated by reference herein.

Further, physiological monitoring systems that include low noise optical sensors and pulse oximetry monitors, such as any of LNOP® adhesive or reusable sensors, SofTouch™ sensors, Hi-Fi Trauma™ or Blue™ sensors; and any of Radical®, SatShare™, Rad-9™, Rad-5™, Rad-5v™ or PPO+™ Masimo SET® pulse oximeters, are all available from Masimo. Physiological monitoring systems including multiple wavelength sensors and corresponding noninvasive blood parameter monitors, such as Rainbow™ adhesive and reusable sensors and RAD-57™ and Radical-7™ monitors for measuring SpO_2, pulse rate (PR), perfusion index (PI), pleth variability index (PVI), signal quality, HbCO and HbMet among other parameters are also available from Masimo.

SUMMARY OF THE INVENTION

Monitor alarms are triggered by out-of-limit parameters and system failures, the latter including monitor or sensor failures or improper sensor placement, to name a few. Alarms can be visual, audible or both. Alarms can also have different levels of priority, which are reflected in the type of visual and audible alarms. In an embodiment, parameters exceeding limits such as low SpO_2, high HbCO, high HbMet and low and high BPM trigger high priority alarms. System failures due to sensor off, no sensor or defective sensor also trigger high priority alarms. Parameters exceeding limits such as high SpO_2, low and high PI, low and high PVI, for example, trigger medium priority alarms. Parameters exceeding limits such as low HbCO and low HbMet along with a system low battery indication are examples of low priority alarms.

An audible alarm may be temporarily suspended by pressing an alarm silence button so as to prevent unnecessary disturbance to the patient and distraction of the caregiver. During alarm suspension, visual alarms remain active. If an alarm condition persists after a predetermined alarm suspend period, the audible alarm resumes. The alarm suspend period is typically long enough to give a caregiver sufficient time to intervene with appropriate patient treatment yet short enough to ensure that patient health is not endangered if intervention is ineffective. For conventional pulse oximetry, an alarm suspend may be, for example, a maximum of 120 seconds.

Alarm suspension on advanced blood parameter monitors is problematic. With conventional pulse oximetry, treatment for abnormal parameter measurements can be quickly applied and a patient response is typically fast. For example, a treatment for low oxygen saturation is the application of an oxygen mask or an increase in oxygen flow. By contrast, the duration of treatment for parameters measured by advanced monitors is highly dependent on the alarm-triggering parameter. For example, the treatment for high methemoglobin is the injection of methylene blue, and the patient response to such an injection is slow. When patient treatment time exceeds the maximum alarm suspend period, an audible alarm will constantly reactivate. Thus, a single alarm suspend duration for all parameters is inadequate to cope with the many different types of parameters measured by advanced monitors.

One aspect of an alarm suspend system for silencing the alarms is an alarm trigger responsive to any of various parameters and predetermined limits corresponding to the parameters, where the parameters are partitioned according to treatment time, i.e. the relative length of time it takes for a person to respond to medical treatment for a parameter measurement outside of the predetermined limits. An

audible alarm is responsive to the alarm trigger. An alarm silence button is actuated so as to suspend the audible alarm. A timer tracks the duration of the suspended alarm and is initiated by actuation of an alarm silence button. The timer retriggers the audible alarm after the timed duration has lapsed/expired. In an embodiment, a long duration suspend time is associated with slow treatment parameters and a short duration suspend time is associated with fast treatment parameters. Fast treatment parameters may include, for example, parameters relating to normal blood hemoglobin constituents and slow treatment parameters may include parameters relating to abnormal blood hemoglobin constituents.

In various embodiments, a short duration suspend time is less than or equal to about two minutes and a long duration suspended time is greater than about two minutes. A default duration associated with the fast treatment parameters is about two minutes and a default duration associated with the slow treatment parameters is about fifteen minutes. The alarm suspend system may also have an alarm suspend override responsive to a predetermined unit change in the parameter triggering a suspended alarm. The override results in reactivation of the suspended alarm. A physiological monitor having an alarm suspend system may also have a pop-up window that appears on the monitor display in response to actuation of the silence button, where the pop-up window presents a choice of alarm suspend durations.

Another aspect of an alarm suspend system is a partition of measured parameters into at least a first group and a second group. An audible alarm is triggered if at least one parameter is outside of predetermined limits. The audible alarm is suspended in response to a silence request. A first duration is associated with the first group and a second duration is associated with the second group. The audible alarm is reactivated after at least one of the first duration and the second duration. The first duration may be set so as to generally correspond to a first range of treatment times for the first group of parameters. Likewise, the second duration may be set so as to generally correspond to a second range of treatment times for the second group of parameters, where the first range of treatment times and the second range of treatment times are non-overlapping.

In various embodiments, suspended audible alarms are overridden if the triggering parameter has greater than a predetermined unit change before the suspended alarm expires according to either the first duration or the second duration. The first and second groups are defined in relation to normal hemoglobin measurements abnormal hemoglobin measurements, respectively. The first duration is set to be less than or equal to two minutes and the second duration is set to be greater than two minutes, with default durations of about two minutes corresponding to the first group and about fifteen minutes corresponding to the second group. In an embodiment, a pop-up window for a monitor display is constructed and the first duration and the second duration are selected from a range of durations presented within the pop-up window.

A further aspect of an alarm suspend system deactivates an audible alarm for one of a short duration and a long duration according to the alarm-triggering parameter. A first group of parameters is associated with the short duration and a second group of parameters is associated with the long duration. The first group and the second group are partitioned according to a fast treatment time and a short treatment time associated with the parameters. An override reactivates the audible alarm if the trigger parameter changes more than a predetermine amount during the corresponding duration. In various embodiments, the first group comprises parameters related to the measurement of normal hemoglobin and the second group comprises parameters related to the measurement of abnormal hemoglobin. The long duration is greater than about 120 seconds and the short duration is less than or equal to about 120 seconds. A pop-up window for the display allows selection of the long duration and the short duration in response to the silence button.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a physiological measurement system utilizing an alarm suspend system;

FIG. **2** is a detailed block diagram of a physiological measurement system utilizing an alarm suspend system;

FIG. **3** is a flow diagram of an alarm suspend system embodiment;

FIG. **4** is a state diagram of an alarm suspend system embodiment; and

FIG. **5** is an illustration of an alarm suspend pop-up window.

DETAILED DESCRIPTION

FIG. **1** illustrates a physiological measurement system **100** that utilizes an alarm suspend system. The physiological measurement system **100** has a noninvasive sensor **105** attached to a tissue site **10**, a physiological monitor **101**, and an interface cable **109** interconnecting the monitor **101** and the sensor **105**. The physiological measurement system **100** may incorporate pulse oximetry in addition to advanced features, such as a multiple wavelength sensor and advanced processes for determining physiological parameters other than or in addition to those of pulse oximetry, such as carboxyhemoglobin, methemoglobin and total hemoglobin, as a few examples.

The monitor **101** has a front panel **110** providing a display **120**, touch keys **130**, controls **140**, a speaker **150**, a sensor port **160** and status indicators **170**. The display **120** shows parameter readouts, limits and waveforms among other items. The display **120** also has touch key icons **122** that indicate touch key **130** functions. The speaker **150** provides an audible alarm in response to physiological measurements that violate preset conditions, such as an out-of-limit parameter, as well as system failures, such as a low battery condition. The controls **140** include an alarm silence button **144** that is pressed to temporarily suspend out-of-limit parameter alarms and system alarms, such as low battery. The display **120** provides visual alarms, which include a bell-shaped alarm status indicator **124** that illuminates during an alarm condition and parameter readouts **210** and limits **220** that flash when parameters are out-of-limit. Status indicators **170** also provide visual alarms. When there are multiple alarm conditions, the parameter displays **202** indicate parameters with the highest alarm priority. Touch keys **130** and corresponding icons **122** include an alarm menu access button for setting alarm conditions, such as high or low alarm limits for SpO_2, HbCO, HbMet, PR and PI. The alarm silence button **144** is pressed to temporarily suspend audible alarms. Advantageously, an alarm suspend system provides a parameter-dependent variation in the alarm suspend duration, as described below, utilizing a common silence button or other suspend initiator.

FIG. **2** illustrates a physiological measurement system **200** including a physiological monitor **201**, a sensor **205** and an interface cable **209**. The sensor **205** is attached to a tissue site, such as a finger **10**, and includes a plurality of emitters

206 irradiating the tissue site **10** with multiple wavelengths of light. The sensor **205** also includes one or more detectors **208** capable of detecting the light after attenuation by the tissue site **10**. The sensor **205** transmits optical radiation at wavelengths other than or including the red and infrared wavelengths utilized in pulse oximeters. The monitor **201** inputs a corresponding sensor signal **211** and determines the relative concentrations of blood constituents other than or in addition to the "normal" blood hemoglobin constituents HbO_2 and Hb, including "abnormal" blood hemoglobin constituents HbCO, HbMet and blood related parameters such as fractional oxygen saturation, total hemoglobin and blood glucose to name a few.

As shown in FIG. **2**, the monitor **201** has a front-end signal conditioner **210**, an A/D converter **220**, emitter drivers **230**, D/A converters **240** and a digital signal processor ("DSP") **250**. In general, the emitter drivers **230** convert digital control signals, via the D/A converters **240**, into analog drive signals capable of driving the sensor emitters **206**. The front-end signal conditioner **210** converts, via the A/D converter **220**, composite analog intensity signal(s) from light sensitive detector(s) **208** into digital data input to the DSP **250**. The emitter drivers **230** and front-end signal conditioner **210** communicate with the sensor **205** via the interface cable **209**.

Also shown in FIG. **2**, the monitor **201** has an instrument manager **260** and a user interface **280**. The user interface **280** includes one or more displays **282**, alarms **284** and user input/output (I/O) **286**. The instrument manager **260** communicates with the DSP **250** to receive parameter data and to present that data on the display **282**. The instrument manager **260** may also store and display historical or trending data related to one or more of the measured parameters or combinations of the measured parameters. The instrument manager **260** also controls audible and visual alarms and indicators **284**. The instrument manager **260** responds to user-actuated keys and communicates with external devices via various I/O ports **286**. Further, the instrument manager **260** executes alarm suspend firmware **270** so as to respond to an alarm silence button press **288**, as described in detail with respect to FIGS. **3-4**.

FIG. **3** generally illustrates an alarm suspend system **300**. Alarm triggers include system failures **338** and out-of-limit parameters **318**. Triggered alarms **340** may be audible, visual or both, and may vary according to priority **342**. Audible alarms may be generated by a monitor front-panel-mounted speaker **150** (FIG. **1**) and may vary in loudness, pitch and sound pattern. Visual alarms may include parameter labels, parameter numerics, symbols and status lights, which can flash and vary in color.

As shown in FIG. **3**, measured parameters **312** are compared **310** to default or user-specified limits **314**. An out-of-limit condition **318** triggers an alarm **340**. An alarm suspend **328** is user-initiated by a silence request **322**. This may be a press of a silence button **144** (FIG. **1**) on a monitor front panel **110** (FIG. **1**). In an embodiment, the alarm suspend **328** silences audible alarms and modifies the display of visual alarms. The alarm suspend **328** is based on a timer **320**, which ends the alarm suspend **328** after a predetermined duration **324**. The duration **324** may be a function of the out-of-limit parameter **312**. In an advantageous embodiment, the duration **324** relates to, or is a function of, the treatment time for the alarm-triggering parameter so as to avoid nuisance alarms while maintaining alarm integrity.

FIG. **4** illustrates an alarm suspend embodiment **400** that operates independently for each measured parameter that

can trigger an alarm. An alarm is initially off **410**. The alarm remains off as long as the parameter is within its set limits **412**. If a parameter is measured outside of its set limits **414**, an alarm is triggered **420**. The alarm may audible, visual or both audible and visual. A user can request to silence the alarm by pressing an alarm silence button **144** (FIG. **1**), for example. The silence request **422** suspends the alarm **430** which turns off audible alarms but, in an embodiment, does not deactivate visual alarms. The audible alarm remains suspended **430** for a predetermined duration **432**. When the suspend duration has passed, the alarm suspend expires **434** and audible alarms are once again activated **420**. The alarm remains on **428** until the triggering parameter is within limits **424** or a user once again requests silence **422**. The alarm suspend **430** deactivates if the measured parameter becomes within limits **438**, such as when the patient condition improves, or if no physiological data is detected **439**, such as no sensor, sensor off, no cable or malfunctioning sensor situations, to name a few. Also, if the measured parameter changes during the alarm suspend **430** by a sufficient out-of-limit amount, an override **436** reactivates the audible alarms **420**.

In an alarm suspend system embodiment, parameters are classified according to the typical time it takes for medical treatment to transition an out-of-limit measurement to a within-limit measurement. Suspend durations **324** (FIG. **3**) are set accordingly. For example, in a two-tier embodiment, relatively slow treatment parameters, such as HbMet, HbCO, Hbt and PVI, are assigned relatively long suspend durations. Similarly, relatively fast treatment parameters, such as SpO_2 and PR, are assigned relatively short suspend durations. In an embodiment, the alarm suspend duration is adjustable for each individual parameter, including 2, 5, 10, 15, 20, 25 and 30 minutes for slow treatment parameters, with a default of 15 minutes; and 30, 60, 90 and 120 seconds for fast treatment parameters, with a default of 120 seconds. These alarm features are only active when alarm limits have been set. Other alarm features apply to both slow treatment and fast treatment parameters. For example, an alarm delay of 0, 5, 10 or 15 seconds applies to all enabled parameters.

In an embodiment, an override **436** occurs if slow treatment parameters such as HbCO, HbMet or PVI increase or Hbt decreases by a certain unit change during the alarm suspend duration. The unit change is adjustable for each parameter, such as from 1-15 in increments of 1. TABLE 1 shows a default embodiment of override unit changes for these parameters.

TABLE 1

Override Unit Changes for Selected Parameters

Parameter	Unit Change	Direction
HbCO	5	Increase
HbMet	2	Increase
Hbt	2	Decrease
PVI	OFF	Increase

FIG. **5** illustrates an alarm suspend window **500** that provides a "pop-up" display so that a monitor user may manually enter an alarm suspend duration. The alarm suspend window **500** appears as a portion of a monitor display **501**, such as the front panel display **120** (FIG. **1**) described above. The pop-up window **500** responds to a suspend request, such as a silence button **144** (FIG. **1**) press. The alarm suspend window **500** has a window identifier **502** and one or more parameter subsections **510**, **520**. Each param-

eter subsection **510**, **520** has a parameter identifier **512**, **522** and corresponding suspend duration options **514**, **524**. In an embodiment, specific suspend times are selected via monitor touch keys **130** (FIG. **1**) as guided by corresponding touch key icons **560**. Selected suspend times are highlighted or otherwise identified and entered, also via a touch key **130** (FIG. **1**). In an alternative embodiment, the monitor display is a touch screen and alarm suspend times are directly entered by a finger press on a specific duration "virtual button" **514**, **524**. Once one or more suspend durations are entered, the pop-up window **500** disappears from the display **501**. The alarm suspend window **500** advantageously allows a user to quickly choose an appropriate alarm suspend duration for the situation at hand, rather than relying on a predetermined or default duration.

An alarm suspend system is described above with respect to alarms triggered by measured parameters and limits associated with those measured parameters. Limits may correspond to levels of a measured parameter, such as a percentage oxygen saturation to name but one example. Limits may also correspond to trends of a measured parameter, such as a rate-of-change of oxygen saturation, for example. Limits may also correspond to patterns in a measured parameter or a comparison of one measured parameter with another measured parameter, as further examples.

An alarm suspend system is described above with respect to a two-tier grouping of parameters, such as slow treatment and fast treatment parameters and alarm suspend durations associated with those groups. Groupings of parameters with respect to alarm suspend durations may be multi-tier, such as slow, medium and fast treatment parameters, to name but one example.

An alarm suspend system has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.

What is claimed is:

1. A physiological measurement system comprising:

a *noninvasive* physiological sensor [including: a plurality of light emitting diodes] configured to [transmit wavelengths of light onto a tissue site of a patient; and at least one detector configured to measure an indication of the wavelengths of light after attenuation by tissue of the patient and] *be positioned on a patient and* output a signal responsive [of the attenuated light] *to a physiological condition of the patient*; and

one or more processors in communication with the *noninvasive* physiological sensor, the one or more processors configured to *electronically*:

determine a measurement of a physiological parameter based at least in part upon the signal;

determine whether an alarm condition exists by determining whether an activation threshold has been satisfied by the measurement of the physiological parameter;

[receive, from a user, an indication of] *access an alarm hold initiator for* a parameter-specific alarm [suspension] *hold* period of time corresponding to the physiological parameter, the parameter-specific alarm [suspension] *hold* period of time being [selected from] *one of* a plurality of parameter-specific alarm [suspension] *hold* periods of time, the parameter-specific alarm [suspension] *hold* period of time being different from at least one other parameter-specific alarm [suspension] *hold* period of time corresponding to at least one other physiological parameter *for which the one or more processors are configured to determine at least one measurement*;

[activate an alarm in response to determining that an alarm activation threshold has been satisfied by the physiological parameter measurement;

receive] *determine that the alarm hold initiator indicates to hold an indication of* an alarm [suspension indication] *for the alarm condition*; [and]

in response to [receiving] *determining that the alarm hold initiator indicates to hold the indication of* the alarm [suspension indication], [suspend] *hold the indication of* the alarm for the [indicated] parameter-specific alarm [suspension] *hold* period of time*; and*

subsequent to the parameter-specific alarm hold period of time passing, activate the indication of the alarm while the measurement of the physiological parameter satisfies the activation threshold.

2. The physiological measurement system of claim **1**, wherein the one or more processors are further configured to:

provide a user interface to the user including at least a plurality of user-selectable elements, each of the *plurality of user*-selectable elements corresponding to one of the plurality of parameter-specific alarm [suspension] *hold* periods of time.

3. The physiological measurement system of claim **2**, wherein providing the user interface further includes:

constructing a pop-up window for a display; and

displaying the plurality of user-selectable elements in the pop-up window.

4. The physiological measurement system of claim **3**, wherein the plurality of user-selectable elements are configured to allow a user to select a specific one of the plurality of parameter-specific alarm [suspension] *hold* periods of time.

5. The physiological measurement system of claim **4**, wherein [the] *a* selected parameter-specific alarm [suspension] *hold* period of time is selected by selection of one of the plurality of user-selectable elements.

6. The physiological measurement system of claim **1**, wherein the one or more processors are further configured to:

associate [the] *a* selected parameter-specific *alarm hold* period of time [is] with the physiological parameter.

7. The physiological measurement system of claim **6**, wherein the selected parameter-specific *alarm hold* period of time is stored in a memory device in communication with the one or more processors.

8. The physiological measurement system of claim **1**, wherein the one or more processors are further configured to:

determine a *measurement of a* second physiological parameter [measurement] based at least in part upon the signal*, the second physiological parameter being different from the physiological parameter*;

determine whether a second alarm condition exists by determining whether a second activation threshold has been satisfied by the measurement of the second physiological parameter;

[receive, from the user,] *access* a second [indication of] *alarm hold initiator for* a second parameter-specific alarm [suspension] *hold* period of time corresponding to the second physiological parameter, the second parameter-specific alarm [suspension] *hold* period of time being [selected from] *one of* a second plurality of parameter-specific alarm [suspension] *hold* periods of time*, the second parameter-specific alarm hold period*

of time being different from the parameter-specific alarm hold period of time corresponding to the physiological parameter;

[activate a second alarm in response to determining a second alarm activation threshold has been satisfied by the second physiological parameter measurement] *determine that the second alarm hold initiator indicates to hold an indication of a second alarm for the second alarm condition*; [and]

in response to [receiving] *determining that the second alarm hold initiator indicates to hold the indication of* the *second* alarm [suspension indication], [suspend] *hold the indication of* the second alarm for the [indicated] second parameter-specific alarm [suspension] *hold* period of time*; and*

subsequent to the second parameter-specific alarm hold period of time passing, activate the indication of the second alarm while the measurement of the second physiological parameter satisfies the second activation threshold.

9. The physiological measurement system of claim **8**, wherein the one or more processors are further configured to:

provide a user interface to the user including at least a first plurality of user-selectable elements and a second plurality of user-selectable elements, wherein each of the first plurality of user-selectable elements corresponds to one of the plurality of parameter-specific alarm [suspension] *hold* periods of time, and each of the second plurality of user-selectable element corresponds to one of the second plurality of parameter-specific alarm [suspension] *hold* periods of time.

10. The physiological measurement system of claim **9**, wherein the one or more processors are further configured to:

construct a pop-up window for a display; and

display both the first and second plurality of user-selectable elements in the pop-up window.

11. The physiological measurement system of claim **10**, wherein [the] *a* selected *first* parameter-specific alarm [suspension] *hold* period of time is selected by selection of one of the first plurality of user-selectable elements, and [the] *a* selected second parameter-specific alarm [suspension] *hold* period of time is selected by selection of one of the second plurality of user-selectable elements.

12. The physiological measurement system of claim **11**, wherein the at least one of the [first] plurality of parameter-specific alarm [suspension] *hold* periods of time is different from any of the second plurality of parameter-specific alarm [suspension] *hold* periods of time.

13. [An] *A* method comprising:

measuring a *first* physiological parameter *and a second physiological parameter* using a patient monitoring device, the patient monitoring device including a processor and a memory device [configured to store a parameter-specific alarm suspension period of time];

[receiving] *accessing*, from [a user] *the memory device*, [an indication of] *a first alarm hold initiator for* a *first* parameter-specific alarm [suspension] *hold* period of time corresponding to the *first* physiological parameter *and a second alarm hold initiator for a second parameter-specific alarm hold period of time corresponding to the second physiological parameter*, [the parameter-specific alarm suspension period of time being selected from a plurality of parameter-specific alarm suspension periods of time,] the *first* parameter-specific alarm [suspension] *hold* period of time being different from [at least one other] *the second* parameter-specific alarm [suspension] *hold* period of time [corresponding to at least one other physiological parameter; activating an alarm in response to determining an alarm activation threshold has been satisfied by the physiological parameter measurement];

[receiving an] *determining that the first alarm hold initiator indicates to hold a first indication of a first* alarm [suspension indication] *for a first alarm condition for the first physiological parameter*; [and]

in response to [receiving] *determining that the first alarm hold initiator indicates to hold the first indication of* the *first* alarm [suspension indication], [suspending] *holding the first indication of* the *first* alarm for the [indicated] *first* parameter-specific alarm [suspension] *hold* period of time*; and*

subsequent to the first parameter-specific alarm hold period of time passing, activating the first indication of the first alarm.

14. The method of claim **13**, wherein the *first* alarm includes an audible component and a visual component, and wherein [suspending] *holding the first indication of* the *first* alarm comprises [suspending] *holding* the audible component and not [suspending] *holding* the visual component.

15. The method of claim **13** further comprising:

providing a user interface to the user including at least a plurality of user-selectable elements, each of the *plurality of user*-selectable elements corresponding to one of [the] *a* plurality of parameter-specific alarm [suspension] *hold* periods of time*,*

wherein the plurality of parameter-specific alarm hold periods of time comprise the first parameter specific alarm hold period of time.

16. The method of claim **15** further comprising:

constructing a pop-up window for a display; and

displaying the plurality of user-selectable elements in the pop-up window.

17. The method of claim **16**, wherein [the] *a* selected parameter-specific alarm [suspension] *hold* period of time is selected by selection of one of the plurality of user-selectable elements.

18. A physiological measurement system comprising:

a physiological sensor [means for outputting] *configured to output* a signal responsive to a [noninvasive measurement of attenuated light transmitted through a tissue site] *physiological condition* of a patient;

a memory configured to store a first alarm activation threshold; and

[a processing means] *one or more processors* in communication with the physiological sensor [means] and configured to:

determine a *first* measurement of [a] *the first measured* physiological parameter based at least in part upon the signal;

determine whether a first alarm condition exists by determining whether the first alarm activation threshold has been satisfied by the first measurement of the first measured physiological parameter;

[receive, from a user, an indication of a] *access a first alarm hold initiator for a first* parameter-specific alarm [suspension] *hold* period of time corresponding to the *first measured* physiological parameter, [the parameter-specific alarm suspension period of time being selected from a plurality of parameter-specific alarm suspension periods of time,] the *first* parameter-specific alarm [suspension] *hold* period of time being different from [at least one other] *a*

second parameter-specific alarm [suspension] *hold* period of time corresponding to [at least one other] *a second measured* physiological parameter *for which the one or more processors are configured to determine a second measurement*;

[activate an alarm in response to determining an alarm activation threshold has been satisfied by the physiological parameter measurement;

receive an] *determine that the first alarm hold initiator indicates to hold activation of a first* alarm [suspension indication] *for the first alarm condition*; [and]

in response to [receiving] *determining that the first alarm hold initiator indicates to hold activation of* the *first* alarm [suspension indication], [suspend] *hold activation of* the *first* alarm for the [indicated] *first* parameter-specific alarm [suspension] *hold* period of time*; and*

activate the first alarm.

19. The physiological measurement system of claim **18**, wherein the [processing means is] *one or more processors are* further configured to:

determine [a] *the* second [physiological parameter] measurement based at least in part upon the signal;

determine whether a second alarm condition exists by determining whether a second alarm activation threshold has been satisfied by the second measurement;

[receive, from the user,] *access* a second [indication of a] *alarm hold initiator for the* second parameter-specific alarm [suspension] *hold* period of time [corresponding to the second physiological parameter, the second parameter-specific alarm suspension period of time being selected from a second plurality of parameter-specific alarm suspension periods of time; activate a second alarm in response to determining a second alarm activation threshold has been satisfied by the second physiological parameter measurement];

determine that the second alarm hold initiator indicates to hold activation of a second alarm for the second alarm condition; and

in response to [receiving] *determining that the second alarm hold initiator indicates to hold activation of* the *second* alarm [suspension indication], [suspend] *hold*

activation of the second alarm for the [indicated] second parameter-specific alarm [suspension] *hold* period of time.

20. The physiological measurement system of claim **19**, wherein the [processing means is] *one or more processors are* further configured to:

provide a user interface to the user including at least a first plurality of user-selectable elements and a second plurality of user-selectable elements, wherein each of the first plurality of user-selectable elements corresponds to one of [the] *a first* plurality of parameter-specific alarm [suspension] *hold* periods of time, and each of the second plurality of user-selectable [element] *elements* corresponds to one of [the] *a* second plurality of parameter-specific alarm [suspension] *hold* periods of time,

wherein the first plurality of parameter-specific alarm hold periods of time comprise the first parameter-specific alarm hold period of time, and the second plurality of parameter-specific alarm hold periods of time comprise the second parameter-specific alarm hold period of time.

21. The physiological measurement system of claim **20**, wherein [the] *a* selected *first* parameter-specific alarm [suspension] *hold* period of time is selected by selection of one of the first plurality of user-selectable elements, and [the] *a* selected second parameter-specific alarm [suspension] *hold* period of time is selected by selection of one of the second plurality of user-selectable elements.

22. The physiological measurement system of claim **21**, wherein at least one of the first plurality of parameter-specific alarm [suspension] *hold* periods of time is different from any of the second plurality of parameter-specific alarm [suspension] *hold* periods of time.

23. The physiological measurement system of claim 1, wherein the one or more processors are further configured to modify a visual indicator for the parameter-specific alarm hold period of time.

24. The physiological measurement system of claim 1, wherein the physiological parameter comprises one of an oxygen saturation, a pulse rate, a perfusion index, a pleth variability index, a carboxyhemoglobin, a methemoglobin, or a total hemoglobin.

* * * * *

US010213108B2

(12) **United States Patent**
Al-Ali

(10) **Patent No.: US 10,213,108 B2**
(45) **Date of Patent: *Feb. 26, 2019**

(54) **ARM MOUNTABLE PORTABLE PATIENT MONITOR**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 169 days.

This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/448,989**

(22) Filed: **Mar. 3, 2017**

(65) **Prior Publication Data**

US 2017/0224262 A1 Aug. 10, 2017

Related U.S. Application Data

(63) Continuation of application No. 14/815,232, filed on Jul. 31, 2015, which is a continuation of application
(Continued)

(51) **Int. Cl.**
A61B 5/1455 (2006.01)
A61B 5/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***A61B 5/0024*** (2013.01); ***A61B 5/002*** (2013.01); ***A61B 5/0004*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC ... A61B 5/0002; A61B 5/0004; A61B 5/0024; A61B 5/02; A61B 5/0205; A61B 5/0402;
(Continued)

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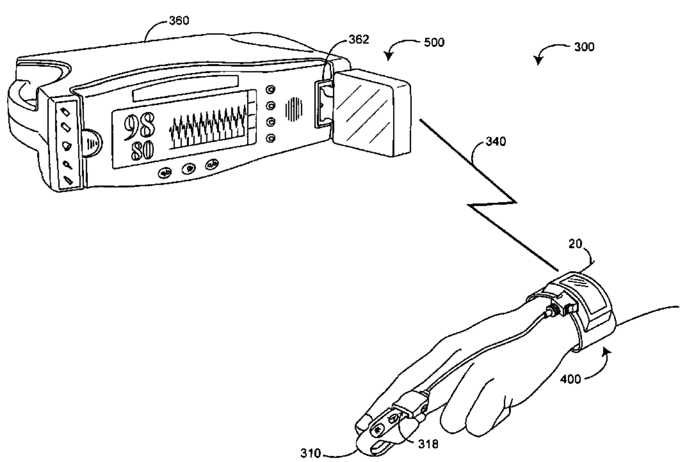
(57) **ABSTRACT**

An arm mountable portable patient monitoring device configured to receive physiological information from a plurality of sensors attached to a patient via wired connections for on-patient monitoring of parameter measurements and wireless transmission of parameter measurements to separate monitoring devices. The arm mountable portable patient monitoring device includes a housing, a strap, a display, a first sensor port positioned on a first side of the housing configured to face toward a hand of the patient when the housing is secured to the arm of the patient, second and third sensor ports configured to receive signals from additional sensor arrangements via a wired connections, one or more signal processing arrangements configured to cause to be displayed measurements of oxygen saturation and pulse rate, and a transmitter configured to wirelessly transmit information indicative of the measurements of oxygen saturation and pulse rate to a separate monitoring device.

22 Claims, 17 Drawing Sheets



Related U.S. Application Data

No. 14/217,788, filed on Mar. 18, 2014, now Pat. No. 9,113,832, which is a continuation of application No. 14/037,137, filed on Sep. 25, 2013, now Pat. No. 9,113,831, which is a continuation of application No. 12/955,826, filed on Nov. 29, 2010, now Pat. No. 8,548,548, which is a continuation of application No. 11/417,006, filed on May 3, 2006, now Pat. No. 7,844,315, which is a continuation of application No. 11/048,330, filed on Feb. 1, 2005, now Pat. No. 7,844,314, which is a continuation of application No. 10/377,933, filed on Feb. 28, 2003, now Pat. No. 6,850,788.

(60) Provisional application No. 60/367,428, filed on Mar. 25, 2002.

(51) **Int. Cl.**

A61B 5/0205	(2006.01)
A61B 5/024	(2006.01)
A61B 5/021	(2006.01)
A61B 5/0404	(2006.01)
A61B 5/0428	(2006.01)
G08B 21/04	(2006.01)
A61B 5/0402	(2006.01)
H04W 4/70	(2018.01)

(52) **U.S. Cl.**

CPC ***A61B 5/0015*** (2013.01); ***A61B 5/0026*** (2013.01); ***A61B 5/021*** (2013.01); ***A61B 5/0205*** (2013.01); ***A61B 5/02427*** (2013.01); ***A61B 5/02438*** (2013.01); ***A61B 5/0404*** (2013.01); ***A61B 5/0428*** (2013.01); ***A61B 5/14552*** (2013.01); ***A61B 5/6824*** (2013.01); ***A61B 5/6826*** (2013.01); ***A61B 5/6831*** (2013.01); ***A61B 5/6838*** (2013.01); ***A61B 5/72*** (2013.01); ***A61B 5/7228*** (2013.01); ***A61B 5/7271*** (2013.01); ***A61B 5/742*** (2013.01); ***A61B 5/7425*** (2013.01); ***A61B 5/7445*** (2013.01); ***A61B 5/7475*** (2013.01); ***G08B 21/0453*** (2013.01); *A61B 5/0402* (2013.01); *A61B 5/1455* (2013.01); *A61B 2560/0214* (2013.01); *A61B 2562/222* (2013.01); *A61B 2562/227* (2013.01); *H04W 4/70* (2018.02); *Y10S 128/903* (2013.01)

(58) **Field of Classification Search**

CPC . A61B 5/1455; A61B 5/14551; A61B 5/6825; A61B 5/6826; A61B 5/6831; A61B 5/72; A61B 2560/0043; A61B 2562/06

See application file for complete search history.

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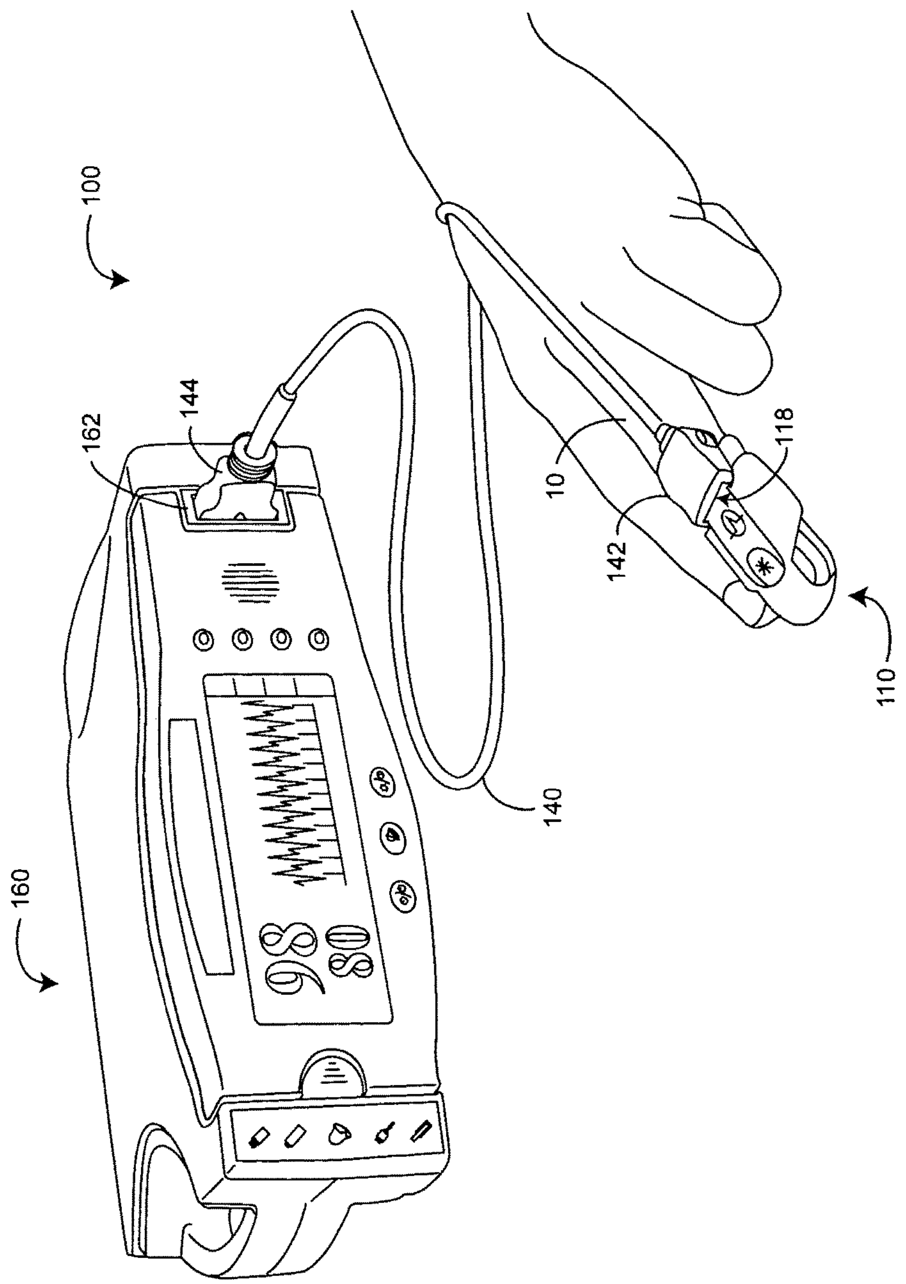


FIG. 1 (Prior Art)

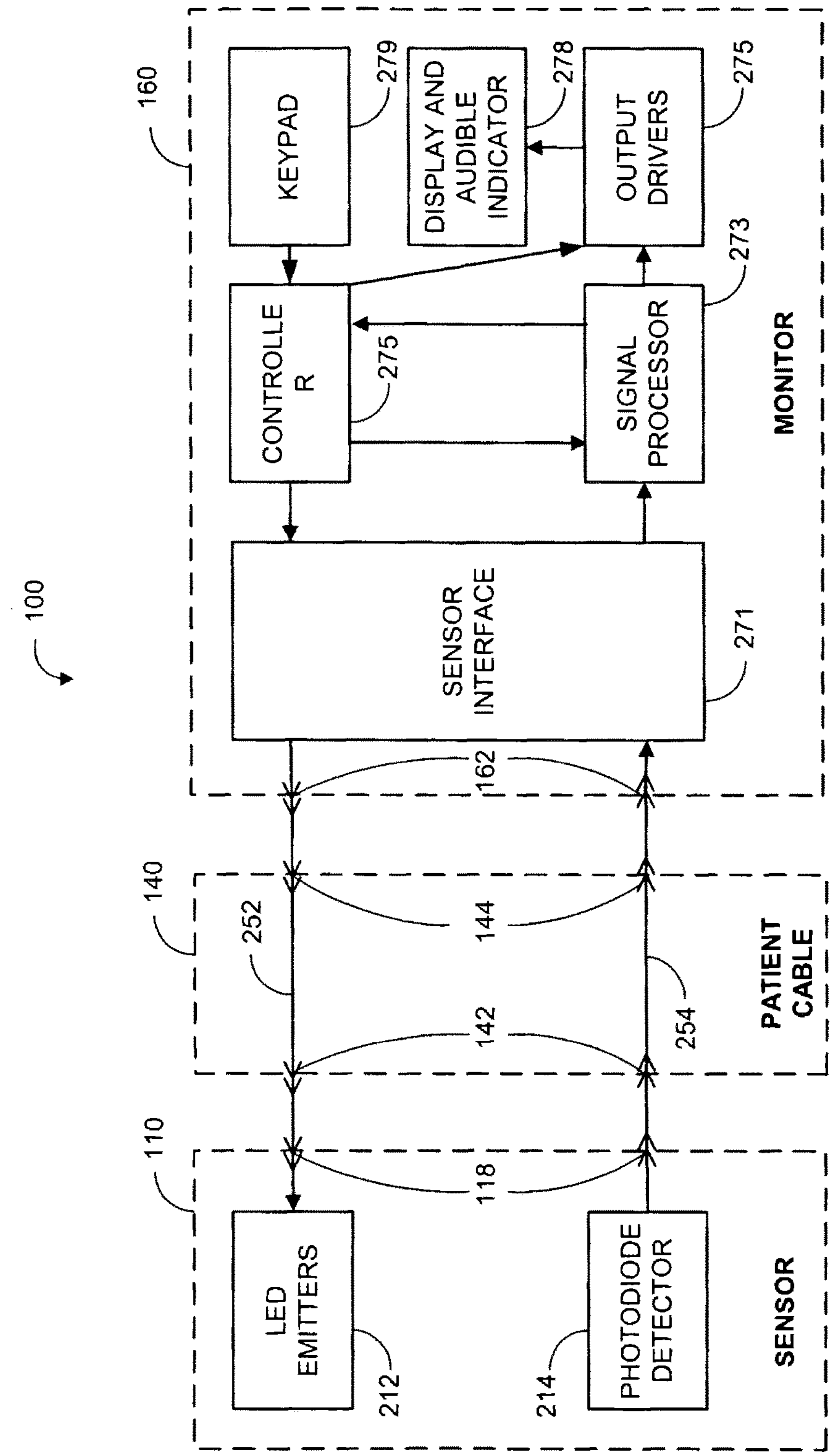


FIG. 2 (Prior Art)

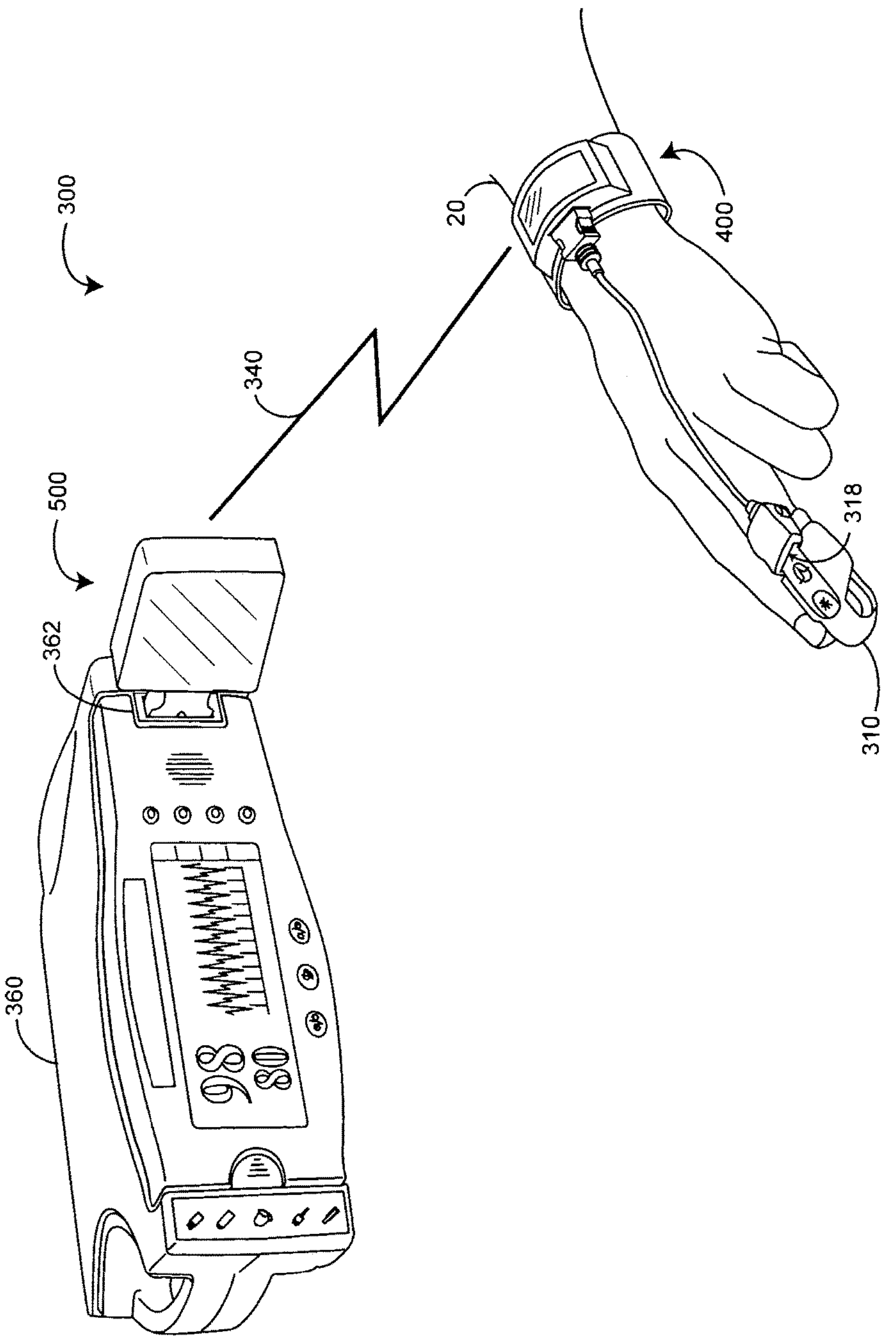


FIG. 3

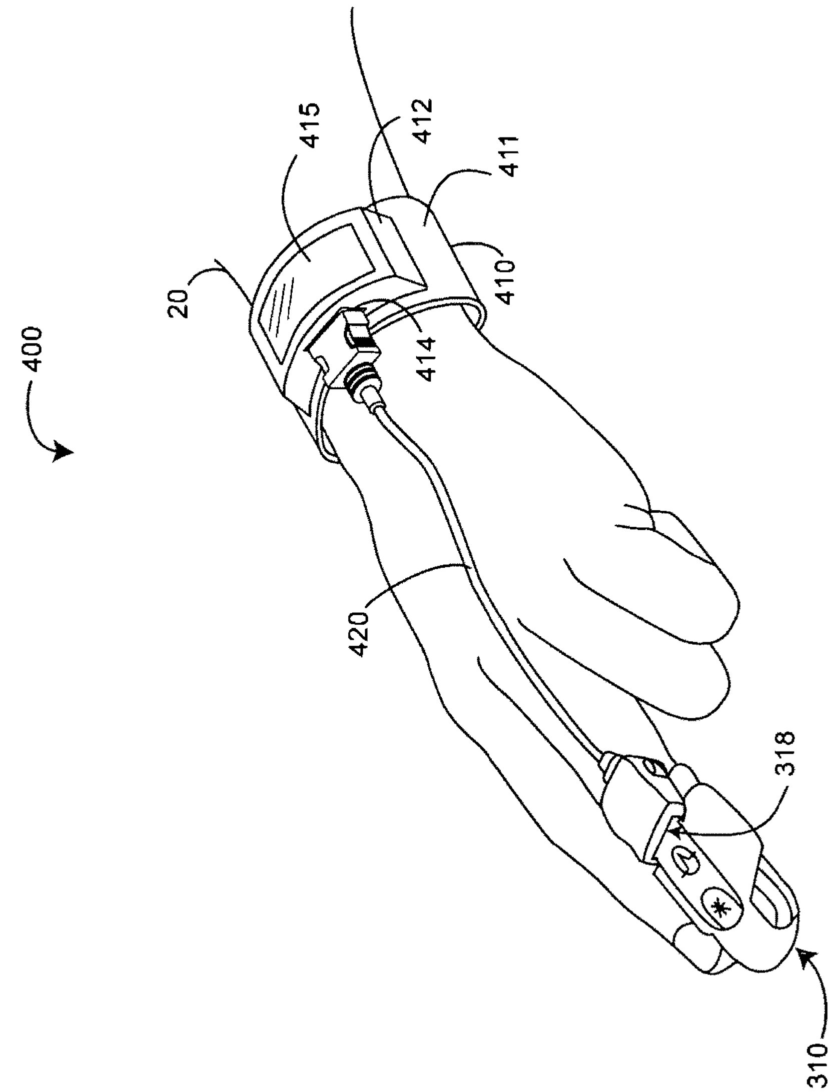


FIG. 4A

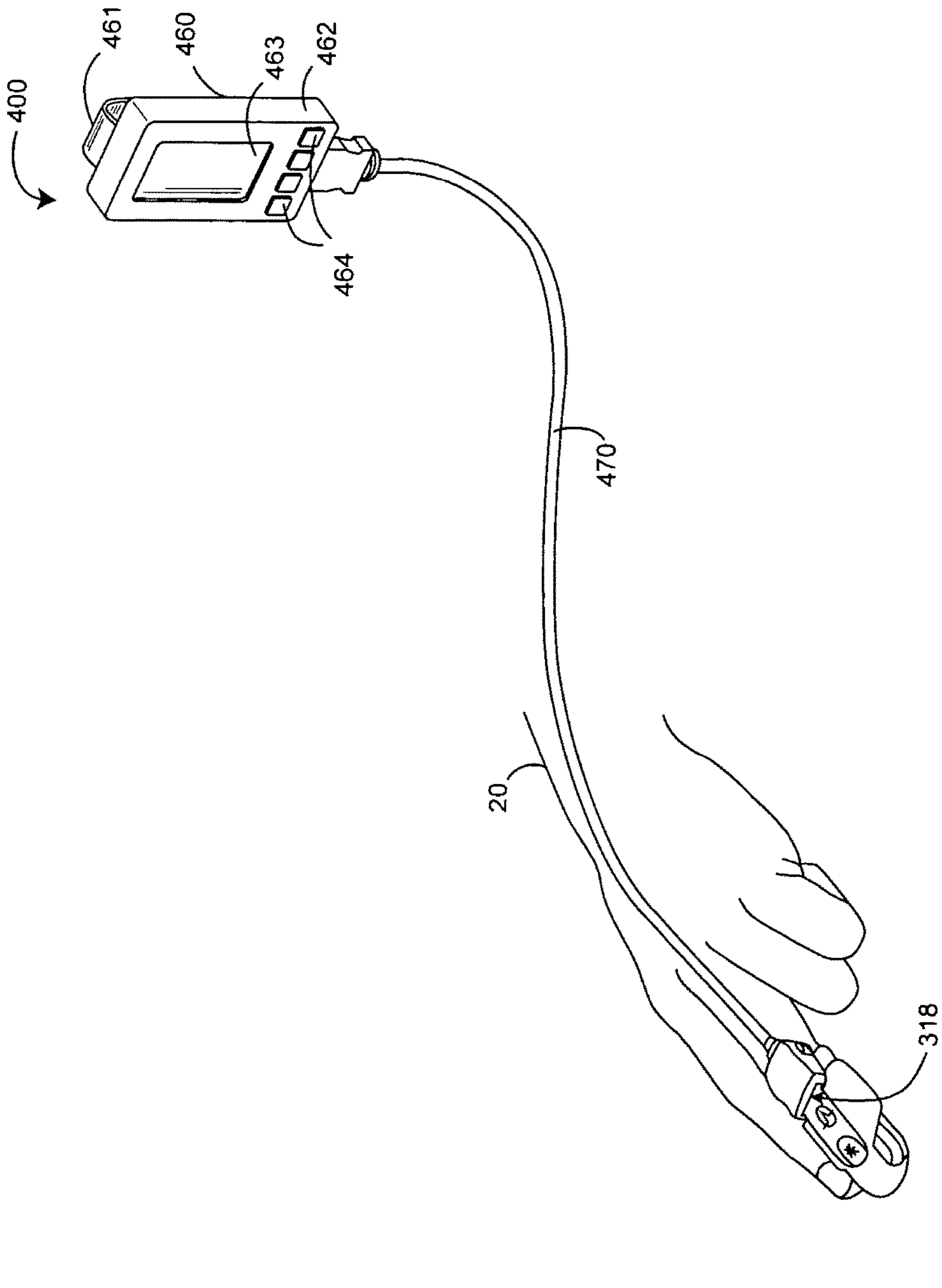


FIG. 4B

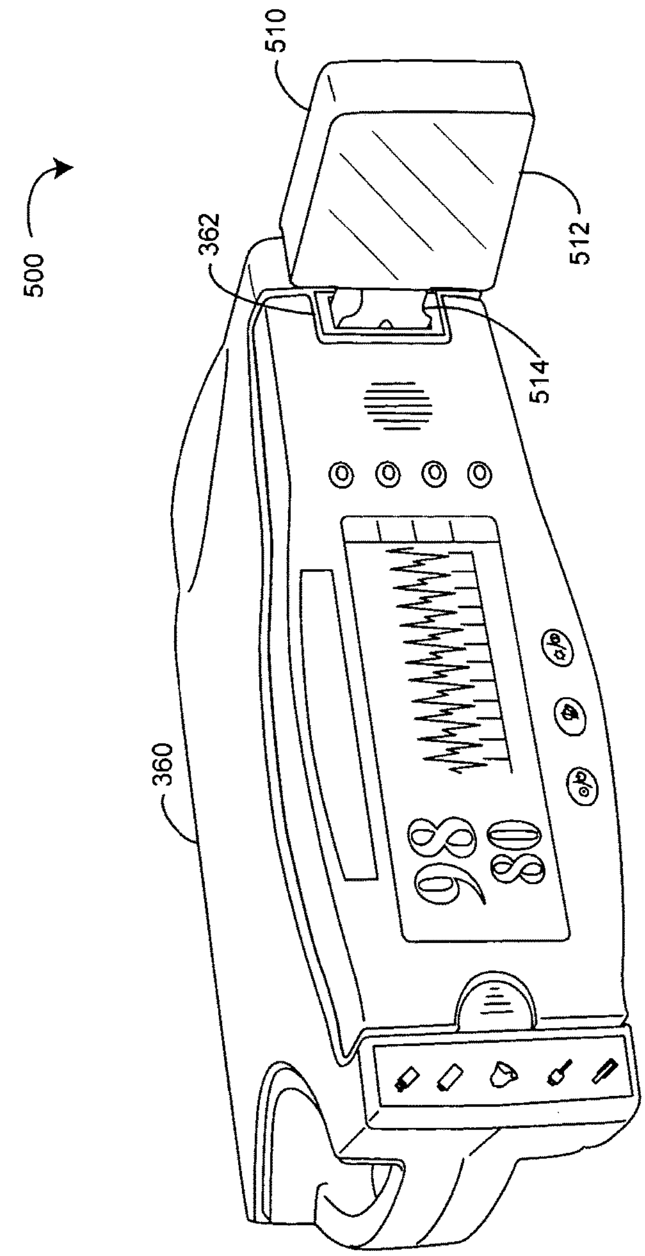


FIG. 5A

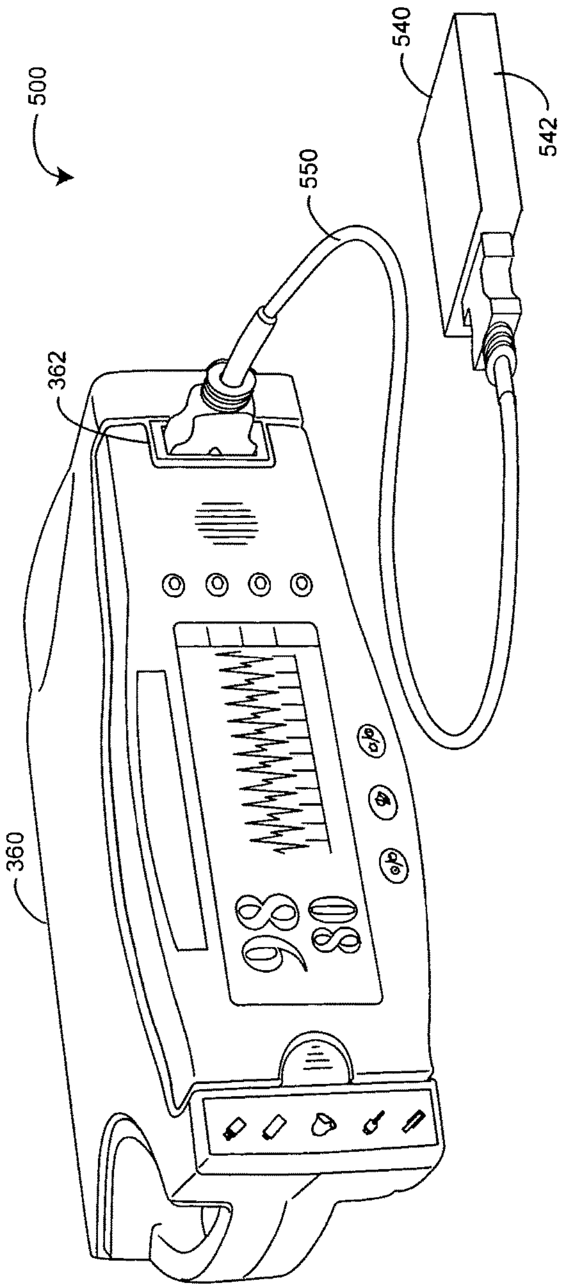


FIG. 5B

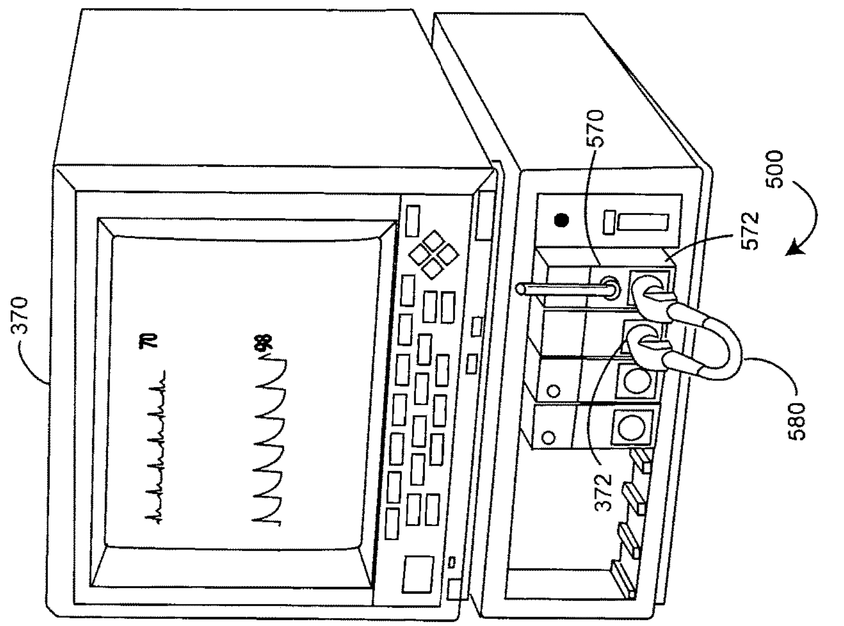
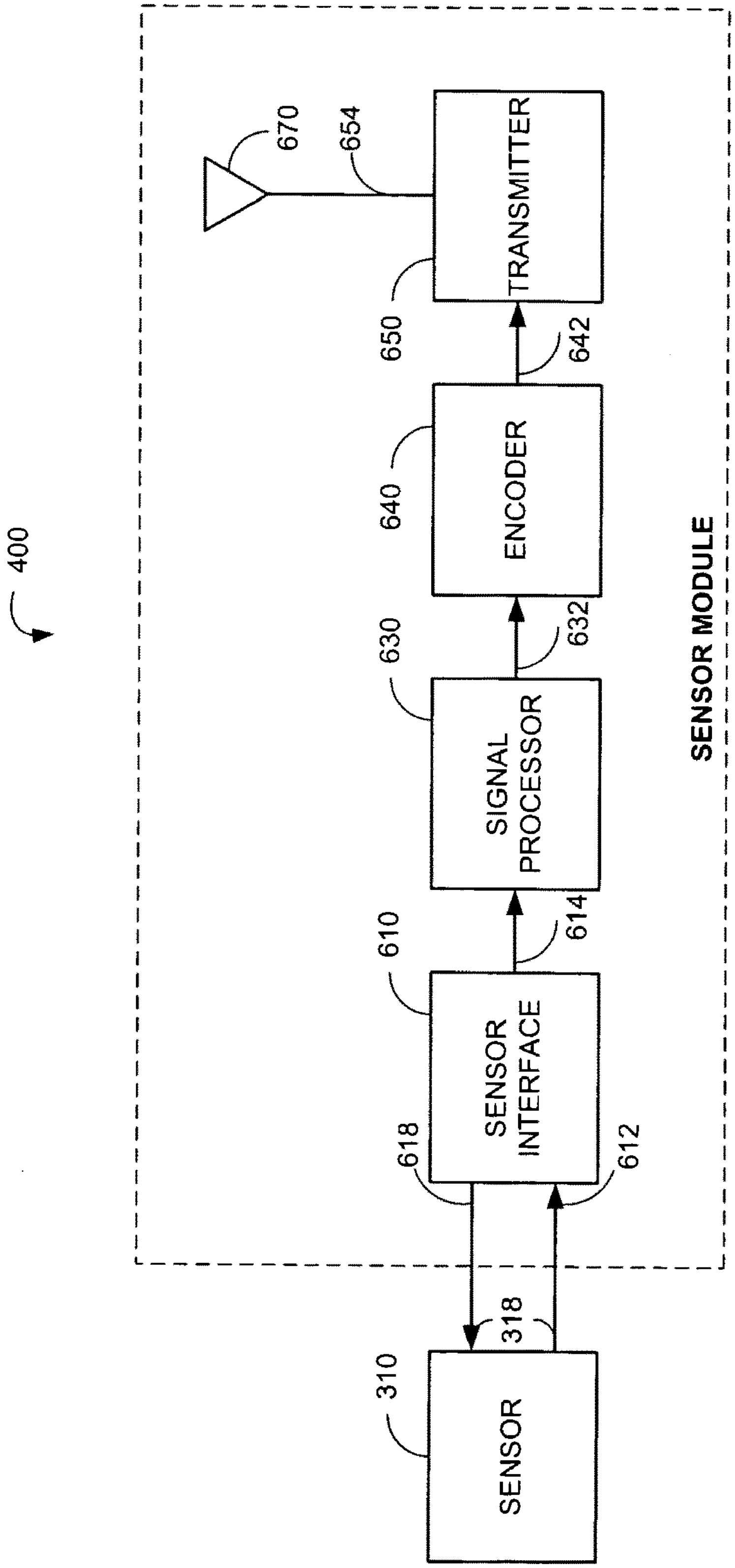


FIG. 5C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TRANSMITTER
ENCODER
SIGNAL PROCESSOR
SENSOR INTERFACE
SENSOR
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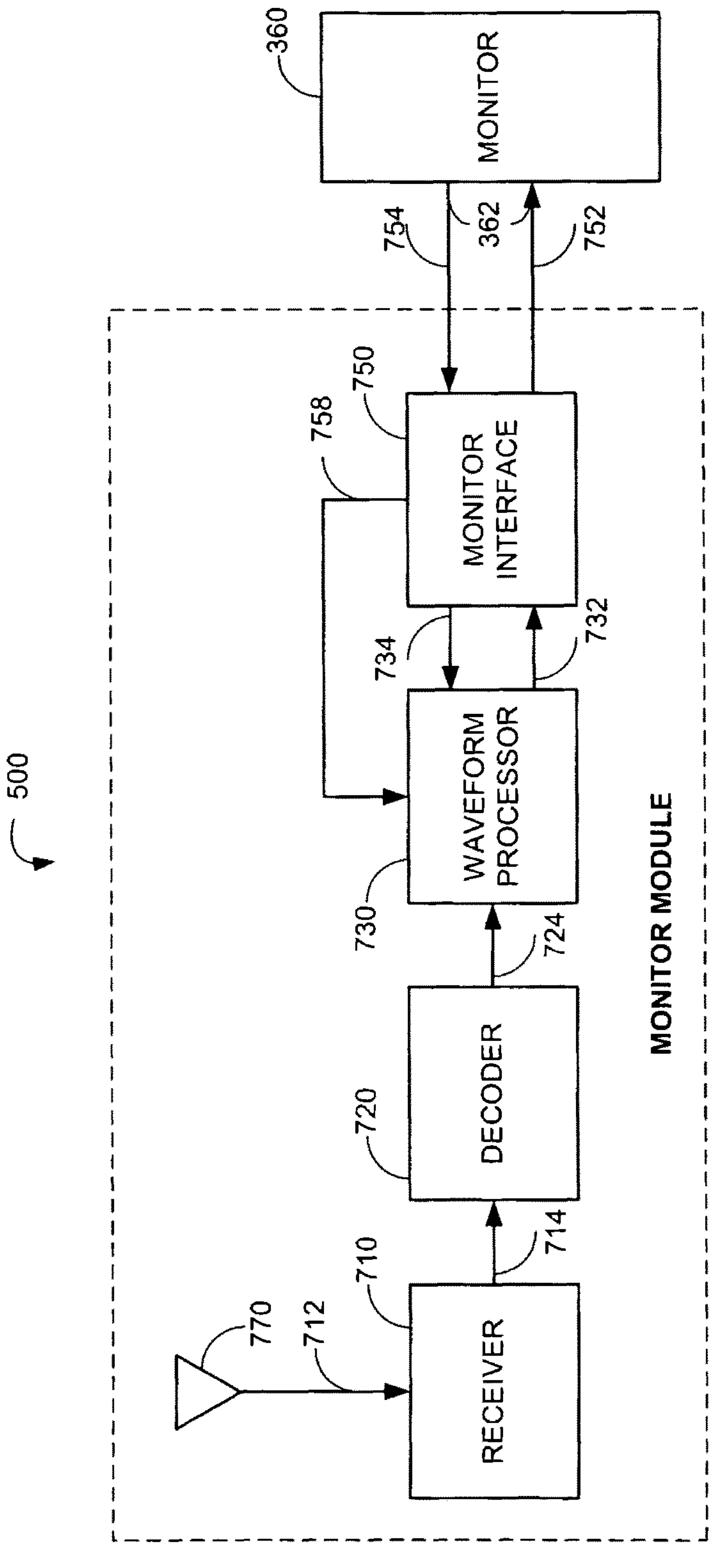
654
650
642
640
632
630
614
610
618
612
318
310

FIG. 6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MONITOR
754
362
752
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758
MONITOR INTERFACE
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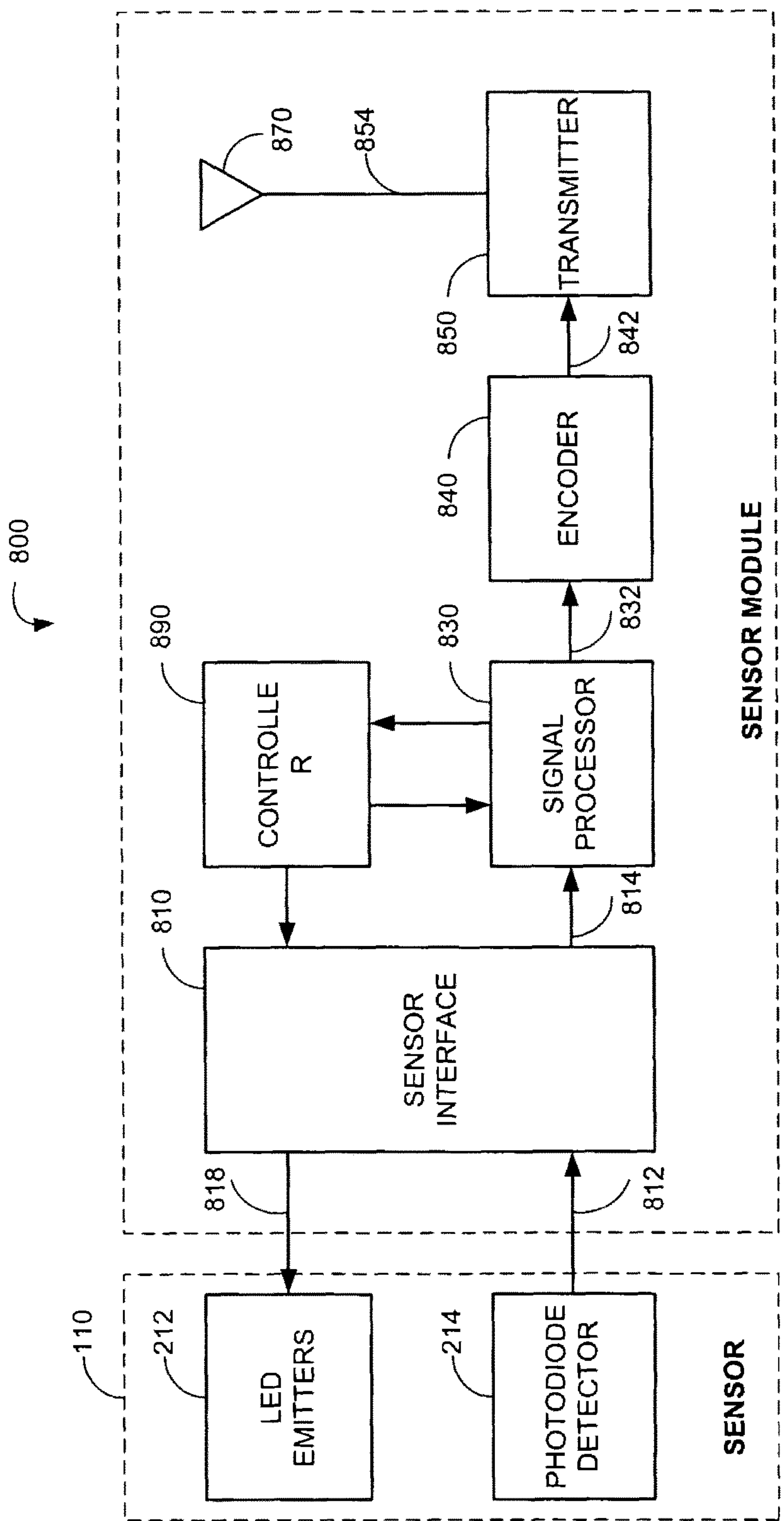
WAVEFORM PROCESSOR
730
724
MONITOR MODULE
DECODER
720
714
710
770
712
RECEIVER

FIG. 7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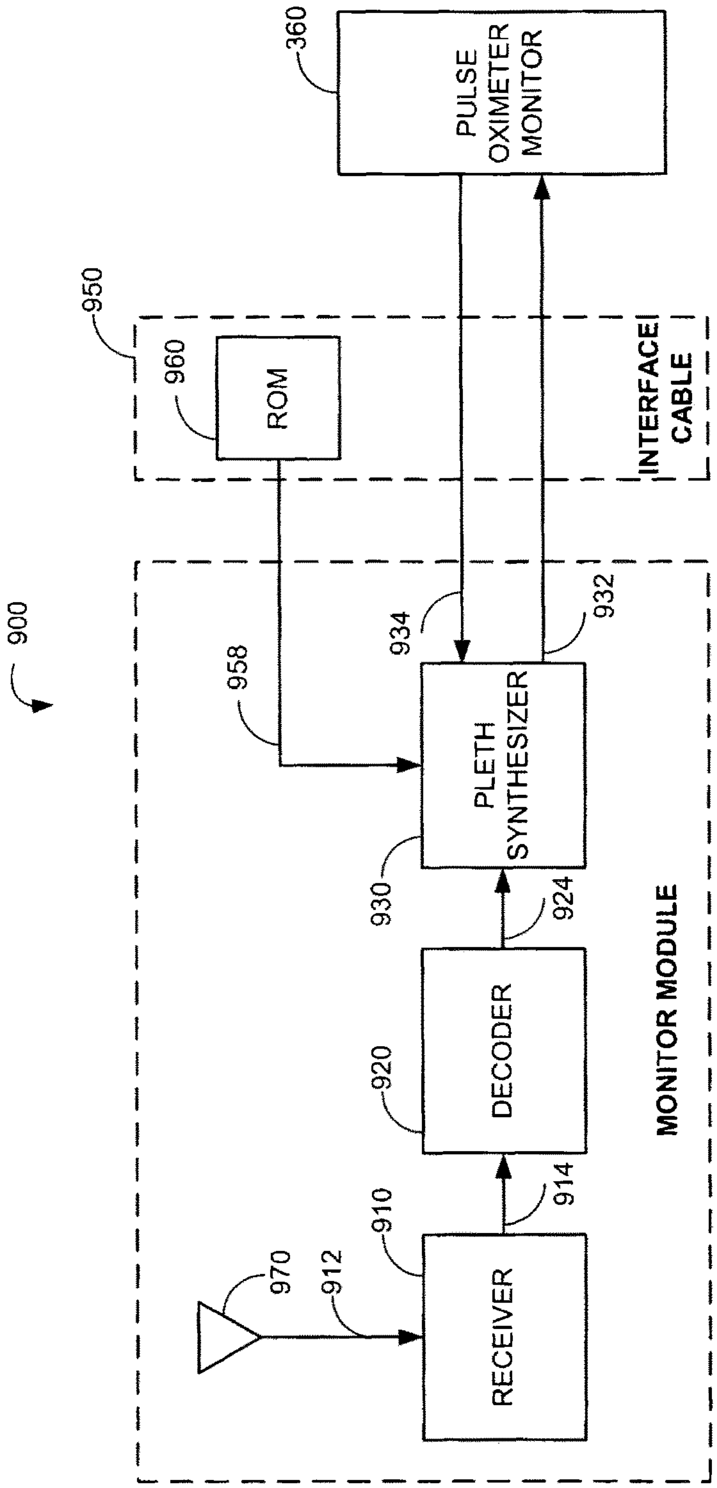
870
854
TRANSMITTER
850
842
ENCODER
840
832
890
CONTROLLE
R
830
SIGNAL
PROCESSOR
810
814
SENSOR
INTERFACE
818
812
SENSOR MODULE
110
212
LED
EMITTERS
214
PHOTODIODE
DETECTOR
SENSOR

FIG. 8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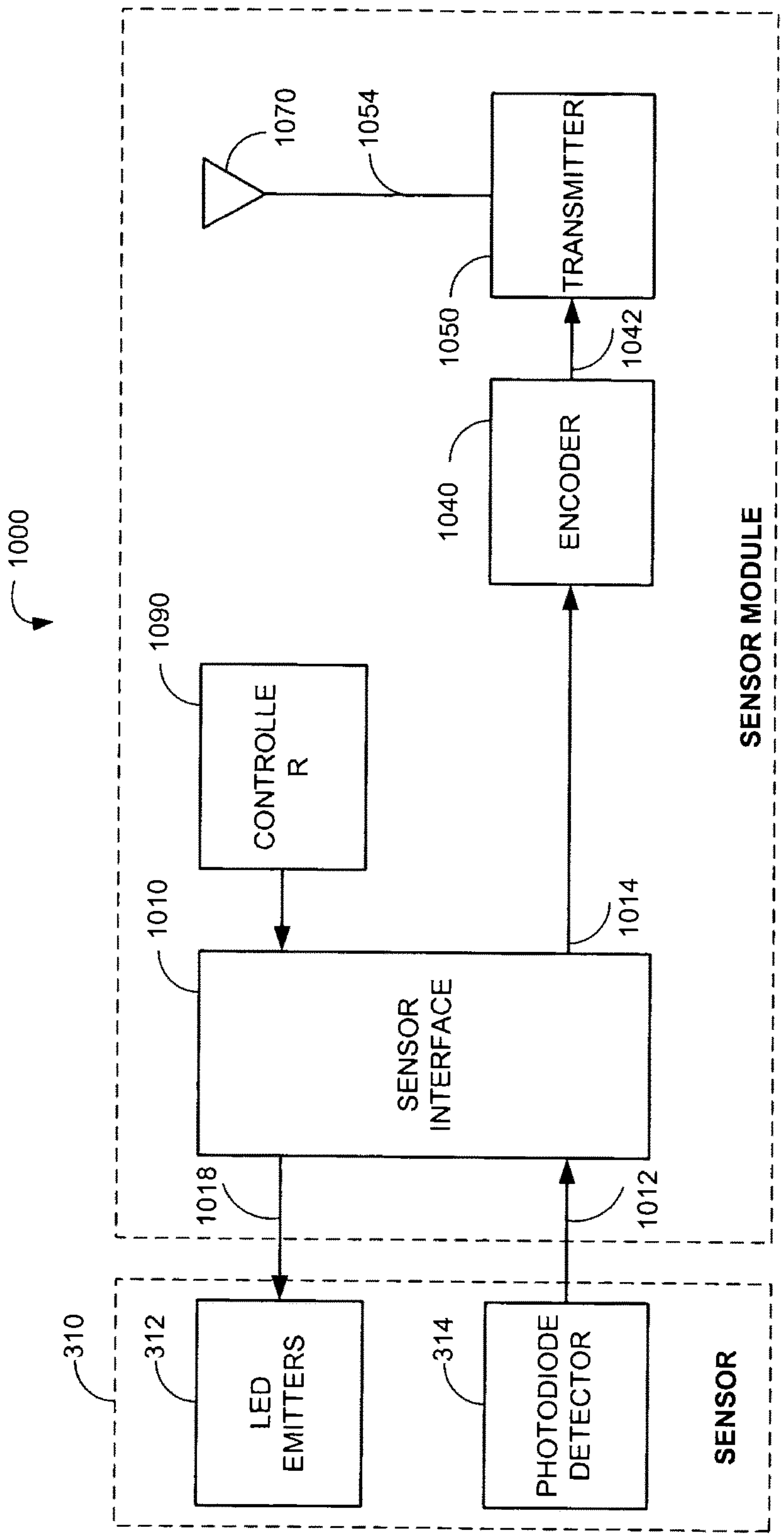
360
PULSE OXIMETER MONITOR
950
960
ROM
INTERFACE CABLE
958
934
932
PLETH SYNTHESIZER
930
924
DECODER
920
914
RECEIVER
910
970
912
MONITOR MODULE

FIG. 9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ENCODER
1040
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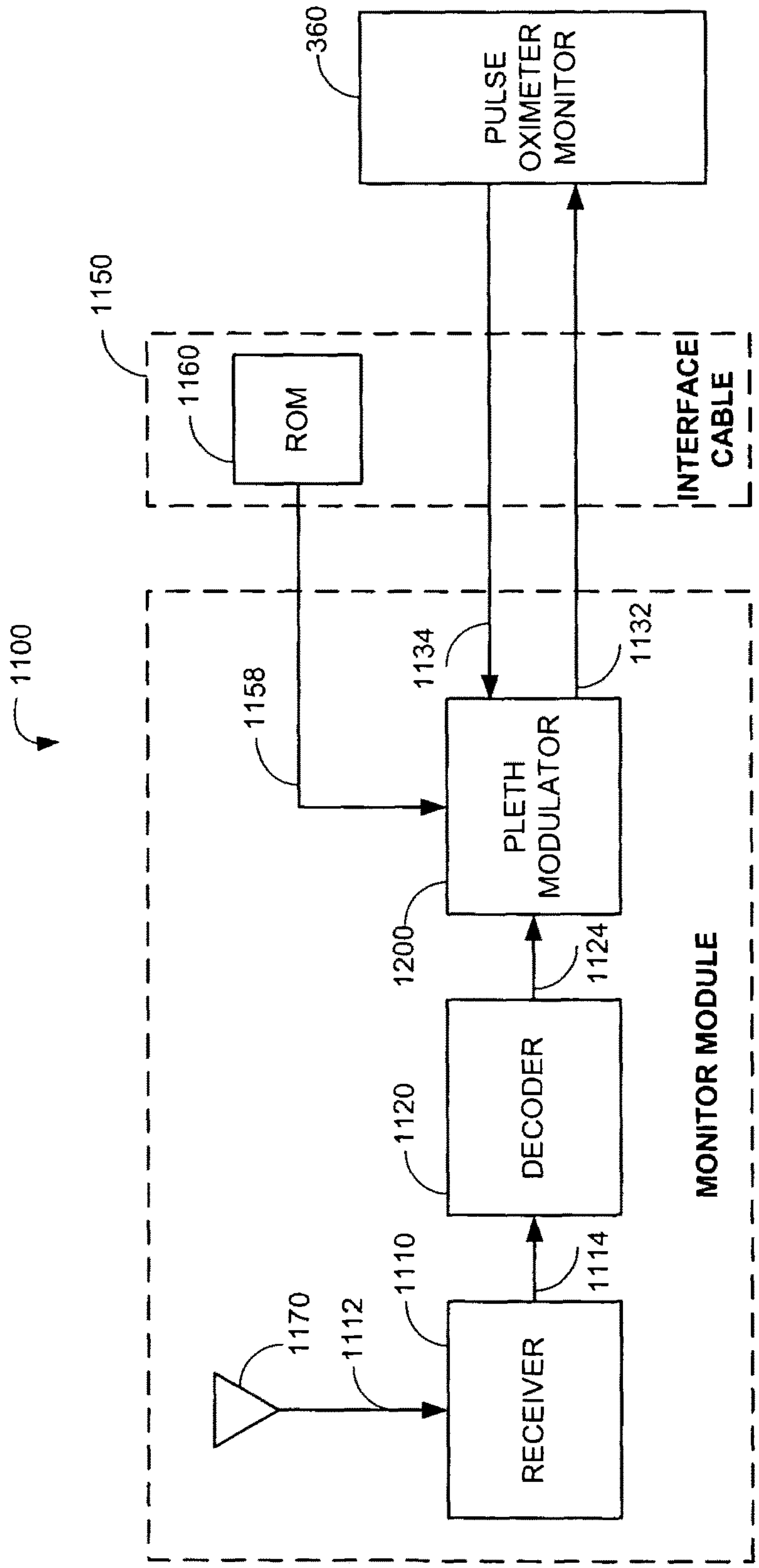
CONTROLLE
R
1010
1014
SENSOR
INTERFACE
1018
1012
SENSOR MODULE
310
312
LED
EMITTERS
314
PHOTODIODE
DETECTOR
SENSOR

FIG. 10


1100
1150
360
PULSE OXIMETER MONITOR
1160
ROM
INTERFACE CABLE
1158
1134
1132
PLETH MODULATOR
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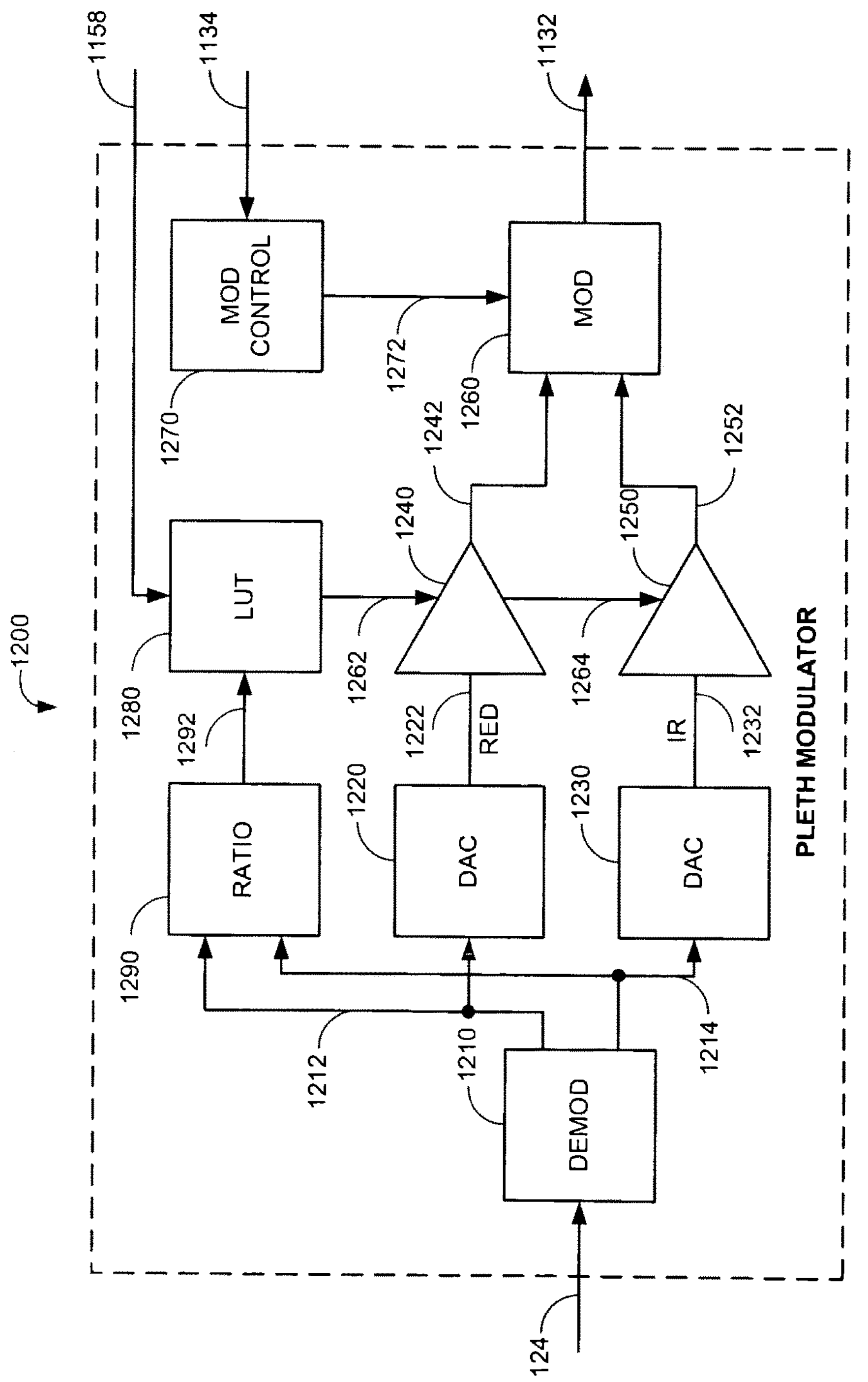
1124
DECODER
1120
MONITOR MODULE
1110
1114
1170
1112
RECEIVER

FIG. 11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1134
1132
MOD CONTROL
MOD
1270
1272
1260
1242
1252
LUT
1240
1250
1280
1262
1264
1200
PLETH MODULATOR
1292
1222
RED
IR
1232
RATIO
DAC
DAC
1220
1230
1290
1212
1210
1214
DEMOD
1124

FIG. 12

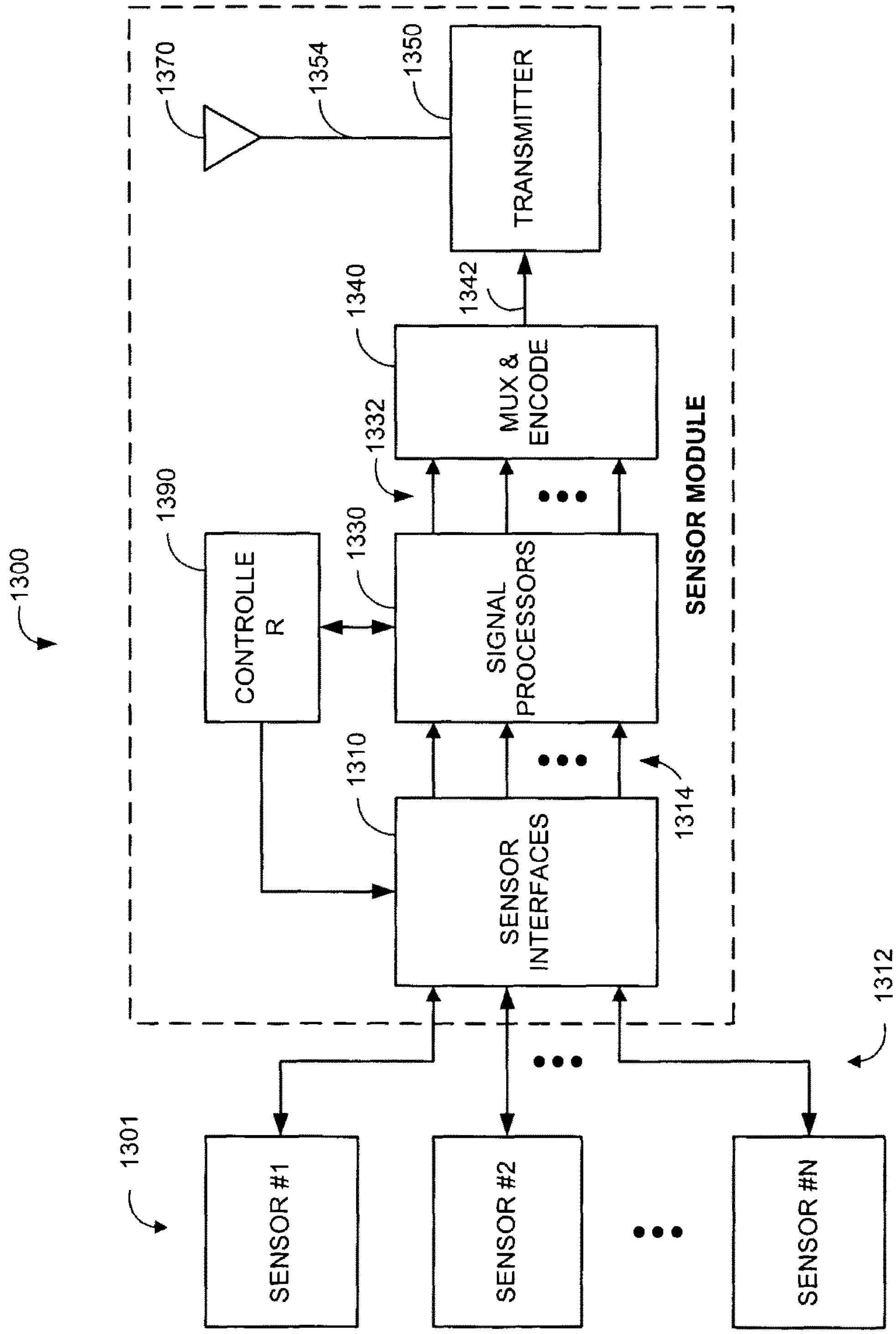
1300
1370
1354
1350
TRANSMITTER
1340
1342
MUX & ENCODE
1332
1390
CONTROLLE R
1330
SIGNAL PROCESSORS
SENSOR MODULE
1310
SENSOR INTERFACES
1314
1312
1301
SENSOR #1
SENSOR #2
SENSOR #N

FIG. 13

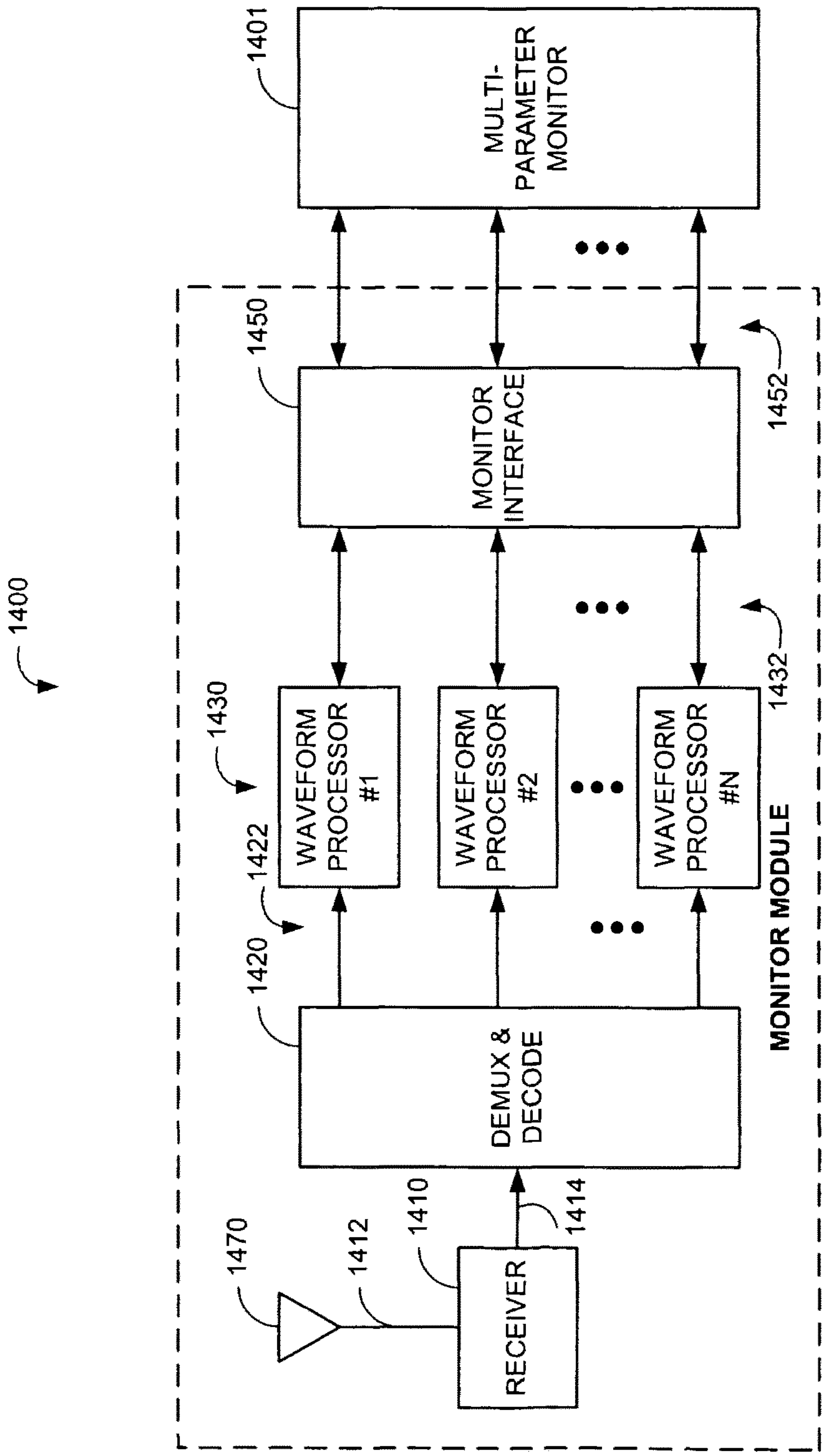
1400
1401
MULTI-PARAMETER MONITOR
1450
MONITOR INTERFACE
1452
1430
WAVEFORM PROCESSOR #1
WAVEFORM PROCESSOR #2
WAVEFORM PROCESSOR #N
1432
1422
1420
DEMUX & DECODE
MONITOR MODULE
1470
1412
1410
RECEIVER
1414

FIG. 14

ARM MOUNTABLE PORTABLE PATIENT MONITOR

REFERENCE TO RELATED APPLICATION

The present application is a continuation of U.S. patent application Ser. No. 14/815,232, filed on Jul. 31, 2015, entitled "Physiological Measurement Communications Adapter," which is a continuation of U.S. patent application Ser. No. 14/217,788, filed on Mar. 18, 2014, entitled "Wrist-Mounted Physiological Measurement Device," now U.S. Pat. No. 9,113,832, which is a continuation of U.S. patent application Ser. No. 14/037,137, filed on Sep. 25, 2013, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 9,113,831, which is a continuation of U.S. patent application Ser. No. 12/955,826, filed on Nov. 29, 2010, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 8,548,548, which is a continuation of U.S. patent application Ser. No. 11/417,006, filed on May 3, 2006, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 7,844,315, which claims priority benefit under 35 U.S.C. § 120 to, and is a continuation of, U.S. patent application Ser. No. 11/048,330, filed Feb. 1, 2005, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 7,844,314, which is a continuation of U.S. patent application Ser. No. 10/377,933, entitled "Physiological Measurement Communications Adapter," now U.S. Pat. No. 6,850,788, which claims priority benefit under 35 U.S.C. § 119(e) from U.S. Provisional Application No. 60/367,428, filed Mar. 25, 2002, entitled "Physiological Measurement Communications Adapter." The present application also incorporates the foregoing utility disclosures herein by reference.

BACKGROUND OF THE INVENTION

Patient vital sign monitoring may include measurements of blood oxygen, blood pressure, respiratory gas, and EKG among other parameters. Each of these physiological parameters typically requires a sensor in contact with a patient and a cable connecting the sensor to a monitoring device. For example, FIGS. **1-2** illustrate a conventional pulse oximetry system **100** used for the measurement of blood oxygen. As shown in FIG. **1**, a pulse oximetry system has a sensor **110**, a patient cable **140** and a monitor **160**. The sensor **110** is typically attached to a finger **10** as shown. The sensor **110** has a plug **118** that inserts into a patient cable socket **142**. The monitor **160** has a socket **162** that accepts a patient cable plug **144**. The patient cable **140** transmits an LED drive signal **252** (FIG. **2**) from the monitor **160** to the sensor **110** and a resulting detector signal **254** (FIG. **2**) from the sensor **110** to the monitor **160**. The monitor **160** processes the detector signal **254** (FIG. **2**) to provide, typically, a numerical readout of the patient's oxygen saturation, a numerical readout of pulse rate, and an audible indicator or "beep" that occurs in response to each arterial pulse.

As shown in FIG. **2**, the sensor **110** has both red and infrared LED emitters **212** and a photodiode detector **214**. The monitor **160** has a sensor interface **271**, a signal processor **273**, a controller **275**, output drivers **276**, a display and audible indicator **278**, and a keypad **279**. The monitor **160** determines oxygen saturation by computing the differential absorption by arterial blood of the two wavelengths emitted by the sensor emitters **212**, as is well-known in the art. The sensor interface **271** provides LED drive current **252** which alternately activates the red and IR LED emitters **212**. The photodiode detector **214** generates a signal **254** corre-

sponding to the red and infrared light energy attenuated from transmission through the patient finger **10** (FIG. **1**). The sensor interface **271** also has input circuitry for amplification, filtering and digitization of the detector signal **254**. The signal processor **273** calculates a ratio of detected red and infrared intensities, and an arterial oxygen saturation value is empirically determined based on that ratio. The controller **275** provides hardware and software interfaces for managing the display and audible indicator **278** and keypad **279**. The display and audible indicator **278** shows the computed oxygen status, as described above, and provides the pulse beep as well as alarms indicating oxygen desaturation events. The keypad **279** provides a user interface for setting alarm thresholds, alarm enablement, and display options, to name a few.

SUMMARY OF THE INVENTION

Conventional physiological measurement systems are limited by the patient cable connection between sensor and monitor. A patient must be located in the immediate vicinity of the monitor. Also, patient relocation requires either disconnection of monitoring equipment and a corresponding loss of measurements or an awkward simultaneous movement of patient equipment and cables. Various devices have been proposed or implemented to provide wireless communication links between sensors and monitors, freeing patients from the patient cable tether. These devices, however, are incapable of working with the large installed base of existing monitors and sensors, requiring caregivers and medical institutions to suffer expensive wireless upgrades. It is desirable, therefore, to provide a communications adapter that is plug-compatible both with existing sensors and monitors and that implements a wireless link replacement for the patient cable.

An aspect of a physiological measurement communications adapter comprises a sensor interface configured to receive a sensor signal. A transmitter modulates a first baseband signal responsive to the sensor signal so as to generate a transmit signal. A receiver demodulates a receive signal corresponding to the transmit signal so as to generate a second baseband signal corresponding to the first baseband signal. Further, a monitor interface is configured to communicate a waveform responsive to the second baseband signal to a sensor port of a monitor. The waveform is adapted to the monitor so that measurements derived by the monitor from the waveform are generally equivalent to measurements derivable from the sensor signal. The communications adapter may further comprise a signal processor having an input in communications with the sensor interface, where the signal processor is operable to derive a parameter responsive to the sensor signal and where the first baseband signal is responsive to the parameter. The parameter may correspond to at least one of a measured oxygen saturation and a pulse rate.

One embodiment may further comprise a waveform generator that synthesizes the waveform from a predetermined shape. The waveform generator synthesizes the waveform at a frequency adjusted to be generally equivalent to the pulse rate. The waveform may have a first amplitude and a second amplitude, and the waveform generator may be configured to adjusted the amplitudes so that measurements derived by the monitor are generally equivalent to a measured oxygen saturation.

In another embodiment, the sensor interface is operable on the sensor signal to provide a plethysmograph signal output, where the first baseband signal is responsive to the

plethysmograph signal. This embodiment may further comprise a waveform modulator that modifies a decoded signal responsive to the second baseband signal to provide the waveform. The waveform modulator may comprise a demodulator that separates a first signal and a second signal from the decoded signal, an amplifier that adjusts amplitudes of the first and second signals to generate a first adjusted signal and a second adjusted signal, and a modulator that combines the first and second adjusted signals into the waveform. The amplitudes of the first and second signals may be responsive to predetermined calibration data for the sensor and the monitor.

An aspect of a physiological measurement communications adapter method comprises the steps of inputting a sensor signal at a patient location, communicating patient data derived from the sensor signal between the patient location and a monitor location, constructing a waveform at the monitor location responsive to the sensor signal, and providing the waveform to a monitor via a sensor port. The waveform is constructed so that the monitor calculates a parameter generally equivalent to a measurement derivable from the sensor signal.

In one embodiment, the communicating step may comprise the substeps of deriving a conditioned signal from the sensor signal, calculating a parameter signal from the conditioned signal, and transmitting the parameter signal from the patient location to the monitor location. The constructing step may comprise the substep of synthesizing the waveform from the parameter signal. In an alternative embodiment, the communicating step may comprise the substeps of deriving a conditioned signal from said sensor signal and transmitting the conditioned signal from the patient location to the monitor location. The constructing step may comprise the substeps of demodulating the conditioned signal and remodulating the conditioned signal to generate the waveform. The providing step may comprise the substeps of inputting a monitor signal from an LED drive output of the sensor port, modulating the waveform in response to the monitor signal, and outputting the waveform on a detector input of the sensor port.

Another aspect of a physiological measurement communications adapter comprises a sensor interface means for inputting a sensor signal and outputting a conditioned signal, a transmitter means for sending data responsive to the sensor signal, and a receiver means for receiving the data. The communications adapter further comprises a waveform processor means for constructing a waveform from the data so that measurements derived by a monitor from the waveform are generally equivalent to measurements derivable from the sensor signal, and a monitor interface means for communicating the waveform to a sensor port of the monitor. The communications adapter may further comprise a signal processor means for deriving a parameter signal from the conditioned signal, where the data comprises the parameter signal. The waveform processor means may comprise a means for synthesizing the waveform from the parameter signal. The data may comprise the conditioned signal, and the waveform processor means may comprise a means for modulating the conditioned signal in response to the monitor.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is an illustration of a prior art pulse oximetry system;

FIG. **2** is a functional block diagram of a prior art pulse oximetry system;

FIG. **3** is an illustration of a physiological measurement communications adapter;

FIGS. **4**A-B are illustrations of communications adapter sensor modules;

FIGS. **5**A-C are illustrations of communications adapter monitor modules;

FIG. **6** is a functional block diagram of a communications adapter sensor module;

FIG. **7** is a functional block diagram of a communications adapter monitor module;

FIG. **8** is a functional block diagram of a sensor module configured to transmit measured pulse oximeter parameters;

FIG. **9** is a functional block diagram of a monitor module configured to received measured pulse oximeter parameters;

FIG. **10** is a functional block diagram of a sensor module configured to transmit a plethysmograph;

FIG. **11** is a functional block diagram of a monitor module configured to receive a plethysmograph;

FIG. **12** is a functional block diagram of a waveform modulator;

FIG. **13** is a functional block diagram of a sensor module configured for multiple sensors; and

FIG. **14** is a functional block diagram of a monitor module configured for multiple sensors.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

Overview

FIG. **3** illustrates one embodiment of a communications adapter. FIGS. **4-5** illustrate physical configurations for a communications adapter. In particular, FIGS. **4**A-B illustrate sensor module configurations and FIGS. **5**A-C illustrate monitor module configurations. FIGS. **6-14** illustrate communications adapter functions. In particular, FIGS. **6-7** illustrate general functions for a sensor module and a monitor module, respectively. FIGS. **8-9** functionally illustrate a communications adapter where derived pulse oximetry parameters, such as saturation and pulse rate are transmitted between a sensor module and a monitor module. Also, FIGS. **10-12** functionally illustrate a communications adapter where a plethysmograph is transmitted between a sensor module and a monitor module. FIGS. **13-14** functionally illustrate a multiple-parameter communications adapter.

FIG. **3** illustrates a communications adapter **300** having a sensor module **400** and a monitor module **500**. The communications adapter **300** communicates patient data derived from a sensor **310** between the sensor module **400**, which is located proximate a patient **20** and the monitor module **500**, which is located proximate a monitor **360**. A wireless link **340** is provided between the sensor module **400** and the monitor module **500**, replacing the conventional patient cable, such as a pulse oximetry patient cable **140** (FIG. **1**). Advantageously, the sensor module **400** is plug-compatible with a conventional sensor **310**. In particular, the sensor connector **318** connects to the sensor module **400** in a similar manner as to a patient cable. Further, the sensor module **400** outputs a drive signal to the sensor **310** and inputs a sensor signal from the sensor **310** in an equivalent manner as a conventional monitor **360**. The sensor module **400** may be battery powered or externally powered. External power may be for recharging internal batteries or for powering the sensor module during operation or both.

As shown in FIG. **3**, the monitor module **500** is advantageously plug-compatible with a conventional monitor **360**. In particular, the monitor's sensor port **362** connects to the

monitor module **500** in a similar manner as to a patient cable, such as a pulse oximetry patient cable **140** (FIG. **1**). Further, the monitor module **500** inputs a drive signal from the monitor **360** and outputs a corresponding sensor signal to the monitor **360** in an equivalent manner as a conventional sensor **310**. As such, the combination sensor module **400** and monitor module **500** provide a plug-compatible wireless replacement for a patient cable, adapting an existing wired physiological measurement system into a wireless physiological measurement system. The monitor module **500** may be battery powered, powered from the monitor, such as by tapping current from a monitor's LED drive, or externally powered from an independent AC or DC power source.

Although a communications adapter **300** is described herein with respect to a pulse oximetry sensor and monitor, one of ordinary skill in the art will recognize that a communications adapter may provide a plug-compatible wireless replace for a patient cable that connects any physiological sensor and corresponding monitor. For example, a communications adapter **300** may be applied to a biopotential sensor, a non-invasive blood pressure (NIBP) sensor, a respiratory rate sensor, a glucose sensor and the corresponding monitors, to name a few.

Sensor Module Physical Configurations

FIGS. **4**A-B illustrate physical embodiments of a sensor module **400**. FIG. **4**A illustrates a wrist-mounted module **410** having a wrist strap **411**, a case **412** and an auxiliary cable **420**. The case **412** contains the sensor module electronics, which are functionally described with respect to FIG. **6**, below. The case **412** is mounted to the wrist strap **411**, which attaches the wrist-mounted module **410** to a patient **20**. The auxiliary cable **420** mates to a sensor connector **318** and a module connector **414**, providing a wired link between a conventional sensor **310** and the wrist-mounted module **410**. Alternatively, the auxiliary cable **420** is directly wired to the sensor module **400**. The wrist-mounted module **410** may have a display **415** that shows sensor measurements, module status and other visual indicators, such as monitor status. The wrist-mounted module **410** may also have keys (not shown) or other input mechanisms to control its operational mode and characteristics. In an alternative embodiment, the sensor **310** may have a tail (not shown) that connects directly to the wrist-mounted module **410**, eliminating the auxiliary cable **420**.

FIG. **4**B illustrates a clip-on module **460** having a clip **461**, a case **462** and an auxiliary cable **470**. The clip **461** attaches the clip-on module **460** to patient clothing or objects near a patient **20**, such as a bed frame. The auxiliary cable **470** mates to the sensor connector **318** and functions as for the auxiliary cable **420** (FIG. **4**A) of the wrist-mounted module **410** (FIG. **4**A), described above. The clip-on module **460** may have a display **463** and keys **464** as for the wrist-mounted module **410** (FIG. **4**A). Either the wrist-mounted module **410** or the clip-on module **460** may have other input or output ports (not shown) that download software, configure the module, or provide a wired connection to other measurement instruments or computing devices, to name a few examples.

Monitor Module Physical Configurations

FIGS. **5**A-C illustrate physical embodiments of a monitor module **500**. FIG. **5**A illustrates a direct-connect module **510** having a case **512** and an integrated monitor connector **514**. The case **512** contains the monitor module electronics, which are functionally described with respect to FIG. **7**, below. The monitor connector **514** mimics that of the monitor end of a patient cable, such as a pulse oximetry patient cable **140** (FIG. **1**), and electrically and mechanically connects the monitor module **510** to the monitor **360** via the monitor's sensor port **362**.

FIG. **5**B illustrates a cable-connect module **540** having a case **542** and an auxiliary cable **550**. The case **542** functions as for the direct-connect module **510** (FIG. **5**A), described above. Instead of directly plugging into the monitor **360**, the cable-connect module **540** utilizes the auxiliary cable **550**, which mimics the monitor end of a patient cable, such as a pulse oximetry patient cable **140** (FIG. **1**), and electrically connects the cable-connect module **540** to the monitor sensor port **362**.

FIG. **5**C illustrates a plug-in module **570** having a plug-in case **572** and an auxiliary cable **580**. The plug-in case **572** is mechanically compatible with the plug-in chassis of a multiparameter monitor **370** and may or may not electrically connect to the chassis backplane. The auxiliary cable **580** mimics a patient cable and electrically connects the plug-in module **570** to the sensor port **372** of another plug-in device. A direct-connect module **510** (FIG. **5**A) or a cable-connect module **540** (FIG. **5**B) may also be used with a multiparameter monitor **370**.

In a multiparameter embodiment, such as described with respect to FIGS. **13-14**, below, a monitor module **500** may connect to multiple plug-in devices of a multiparameter monitor **370**. For example, a cable-connect module **540** (FIG. **5**B) may have multiple auxiliary cables **550** (FIG. **5**B) that connect to multiple plug-in devices installed within a multiparameter monitor chassis. Similarly, a plug-in module **570** may have one or more auxiliary cables **580** with multiple connectors for attaching to the sensor ports **372** of multiple plug-in devices.

Communications Adapter Functions

FIGS. **6-7** illustrate functional embodiments of a communications adapter. FIG. **6** illustrates a sensor module **400** having a sensor interface **610**, a signal processor **630**, an encoder **640**, a transmitter **650** and a transmitting antenna **670**. A physiological sensor **310** provides an input sensor signal **612** at the sensor connector **318**. Depending on the sensor **310**, the sensor module **400** may provide one or more drive signals **618** to the sensor **310**. The sensor interface **610** inputs the sensor signal **612** and outputs a conditioned signal **614**. The conditioned signal **614** may be coupled to the transmitter **650** or further processed by a signal processor **630**. If the sensor module configuration utilizes a signal processor **630**, it derives a parameter signal **632** responsive to the sensor signal **612**, which is then coupled to the transmitter **650**. Regardless, the transmitter **650** inputs a baseband signal **642** that is responsive to the sensor signal **612**. The transmitter **650** modulates the baseband signal **642** with a carrier to generate a transmit signal **654**. The transmit signal **654** may be derived by various amplitude, frequency or phase modulation schemes, as is well known in the art. The transmit signal **654** is coupled to the transmit antenna **670**, which provides wireless communications to a corresponding receive antenna **770** (FIG. **7**), as described below.

As shown in FIG. **6**, the sensor interface **610** conditions and digitizes the sensor signal **612** to generate the conditioned signal **614**. Sensor signal conditioning may be performed in the analog domain or digital domain or both and may include amplification and filtering in the analog domain and filtering, buffering and data rate modification in the digital domain, to name a few. The resulting conditioned signal **614** is responsive to the sensor signal **612** and may be used to calculate or derive a parameter signal **632**.

Further shown in FIG. **6**, the signal processor **630** performs signal processing on the conditioned signal **614** to

generate the parameter signal **632**. The signal processing may include buffering, digital filtering, smoothing, averaging, adaptive filtering and frequency transforms to name a few. The resulting parameter signal **632** may be a measurement calculated or derived from the conditioned signal, such as oxygen saturation, pulse rate, blood glucose, blood pressure and EKG to name a few. Also, the parameter signal **632** may be an intermediate result from which the above-stated measurements may be calculated or derived.

As described above, the sensor interface **610** performs mixed analog and digital pre-processing of an analog sensor signal and provides a digital output signal to the signal processor **630**. The signal processor **630** then performs digital post-processing of the front-end processor output. In alternative embodiments, the input sensor signal **612** and the output conditioned signal **614** may be either analog or digital, the front-end processing may be purely analog or purely digital, and the back-end processing may be purely analog or mixed analog or digital.

In addition, FIG. **6** shows an encoder **640**, which translates a digital word or serial bit stream, for example, into the baseband signal **642**, as is well-known in the art. The baseband signal **642** comprises the symbol stream that drives the transmit signal **654** modulation, and may be a single signal or multiple related signal components, such as in-phase and quadrature signals. The encoder **640** may include data compression and redundancy, also well-known in the art.

FIG. **7** illustrates a monitor module **500** having a receive antenna **770**, a receiver **710**, a decoder **720**, a waveform processor **730** and a monitor interface **750**. A receive signal **712** is coupled from the receive antenna **770**, which provides wireless communications to a corresponding transmit antenna **670** (FIG. **6**), as described above. The receiver **710** inputs the receive signal **712**, which corresponds to the transmit signal **654** (FIG. **6**). The receiver **710** demodulates the receive signal to generate a baseband signal **714**. The decoder **720** translates the symbols of the demodulated baseband signal **714** into a decoded signal **724**, such as a digital word stream or bit stream. The waveform processor **730** inputs the decoded signal **724** and generates a constructed signal **732**. The monitor interface **750** is configured to communicate the constructed signal **732** to a sensor port **362** of a monitor **360**. The monitor **360** may output a sensor drive signal **754**, which the monitor interface **750** inputs to the waveform processor **730** as a monitor drive signal **734**. The waveform processor **730** may utilize the monitor drive signal **734** to generate the constructed signal **732**. The monitor interface **750** may also provide characterization information **758** to the waveform processor **730**, relating to the monitor **360**, the sensor **310** or both, that the waveform processor **730** utilizes to generate the constructed signal **732**.

The constructed signal **732** is adapted to the monitor **360** so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent to measurements derivable from the sensor signal **612** (FIG. **6**). Note that the sensor **310** (FIG. **6**) may or may not be directly compatible with the monitor **360**. If the sensor **310** (FIG. **6**) is compatible with the monitor **360**, the constructed signal **732** is generated so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent (within clinical significance) with those derivable directly from the sensor signal **612** (FIG. **6**). If the sensor **310** (FIG. **6**) is not compatible with the monitor **360**, the constructed signal **732** is generated so that measurements derived by the monitor **360** from the constructed signal **732** are generally equivalent to those derivable directly from the sensor signal **612** (FIG. **6**) using a compatible monitor.

Wireless Pulse Oximetry

FIGS. **8-11** illustrate pulse oximeter embodiments of a communications adapter. FIGS. **8-9** illustrate a sensor module and a monitor module, respectively, configured to communicate measured pulse oximeter parameters. FIG. **10-11** illustrate a sensor module and a monitor module, respectively, configured to communicate a plethysmograph signal.

Parameter Transmission

FIG. **8** illustrates a pulse oximetry sensor module **800** having a sensor interface **810**, signal processor **830**, encoder **840**, transmitter **850**, transmitting antenna **870** and controller **890**. The sensor interface **810**, signal processor **830** and controller **890** function as described with respect to FIG. **2**, above. The sensor interface **810** communicates with a standard pulse oximetry sensor **310**, providing an LED drive signal **818** to the LED emitters **312** and receiving a sensor signal **812** from the detector **314** in response. The sensor interface **810** provides front-end processing of the sensor signal **812**, also described above, providing a plethysmograph signal **814** to the signal processor **830**. The signal processor **830** then derives a parameter signal **832** that comprises a real time measurement of oxygen saturation and pulse rate. The parameter signal **832** may include other parameters, such as measurements of perfusion index and signal quality. In one embodiment, the signal processor is an MS-5 or MS-7 board available from Masimo Corporation, Irvine, Calif.

As shown in FIG. **8**, the encoder **840**, the transmitter **850** and the transmitting antenna **870** function as described with respect to FIG. **6**, above. For example, the parameter signal **832** may be a digital word stream that is serialized into a bit stream and encoded into a baseband signal **842**. The baseband signal **842** may be, for example, two bit symbols that drive a quadrature phase shift keyed (QPSK) modulator in the transmitter **850**. Other encodings and modulations are also applicable, as described above. The transmitter **850** inputs the baseband signal **842** and generates a transmit signal **854** that is a modulated carrier having a frequency suitable for short-range transmission, such as within a hospital room, doctor's office, emergency vehicle or critical care ward, to name a few. The transmit signal **854** is coupled to the transmit antenna **870**, which provides wireless communications to a corresponding receive antenna **970** (FIG. **9**), as described below.

FIG. **9** illustrates a monitor module **900** having a receive antenna **970**, a receiver **910**, a decoder **920**, a waveform generator **930** and an interface cable **950**. The receive antenna **970**, receiver **910** and decoder **920** function as described with respect to FIG. **7**, above. In particular, the receive signal **912** is coupled from the receive antenna **970**, which provides wireless communications to a corresponding transmit antenna **870** (FIG. **8**). The receiver **910** inputs the receive signal **912**, which corresponds to the transmit signal **854** (FIG. **8**). The receiver **810** demodulates the receive signal **912** to generate a baseband signal **914**. Not accounting for transmission errors, the baseband signal **914** corresponds to the sensor module baseband signal **842** (FIG. **8**), for example a symbol stream of two bits each. The decoder **920** assembles the baseband signal **914** into a parameter signal **924**, which, for example, may be a sequence of digital words corresponding to oxygen saturation and pulse rate. Again, not accounting for transmission errors, the monitor module parameter signal **924** corresponds to the sensor module parameter signal **832** (FIG. **8**), derived by the signal processor **830** (FIG. **8**).

Also shown in FIG. **9**, the waveform generator **930** is a particular embodiment of the waveform processor **730** (FIG. **7**) described above. The waveform generator **930** generates a synthesized waveform **932** that the pulse oximeter monitor **360** can process to calculate SpO_2 and pulse rate values or exception messages. In the present embodiment, the waveform generator output does not reflect a physiological waveform. In particular, the synthesized waveform is not physiological data from the sensor module **800**, but is a waveform synthesized from predetermined stored waveform data to cause the monitor **360** to calculate oxygen saturation and pulse rate equivalent to or generally equivalent (within clinical significance) to that calculated by the signal processor **830** (FIG. **8**). The actual intensity signal from the patient received by the detector **314** (FIG. **8**) is not provided to the monitor **360** in the present embodiment. Indeed, the waveform provided to the monitor **360** will usually not resemble a plethysmographic waveform or other physiological data from the patient to whom the sensor module **800** (FIG. **8**) is attached.

The synthesized waveform **932** is modulated according to the drive signal input **934**. That is, the pulse oximeter monitor **360** expects to receive a red and IR modulated intensity signal originating from a detector, as described with respect to FIGS. **1-2**, above. The waveform generator **930** generates the synthesized waveform **932** with a predetermined shape, such as a triangular or sawtooth waveform stored in waveform generator memory or derived by a waveform generator algorithm. The waveform is modulated synchronously with the drive input **934** with first and second amplitudes that are processed in the monitor **360** as red and IR portions of a sensor signal. The frequency and the first and second amplitudes are adjusted so that pulse rate and oxygen saturation measurements derived by the pulse oximeter monitor **360** are generally equivalent to the parameter measurements derived by the signal processor **830** (FIG. **8**), as described above. One embodiment of a waveform generator **930** is described in U.S. Patent Application No. 60/117,097 entitled "Universal/Upgrading Pulse Oximeter," assigned to Masimo Corporation, Irvine, Calif. and incorporated by reference herein. Although the waveform generator **930** is described above as synthesizing a waveform that does not resemble a physiological signal, one of ordinary skill will recognize that another embodiment of the waveform generator **930** could incorporate, for example, a plethysmograph simulator or other physiological signal simulator.

Further shown in FIG. **9**, the interface cable **950** functions in a manner similar to the monitor interface **750** (FIG. **7**) described above. The interface cable **950** is configured to communicate the synthesized waveform **932** to the monitor **360** sensor port and to communicate the sensor drive signal **934** to the waveform generator **930**. The interface cable **950** may include a ROM **960** that contains monitor and sensor characterization data. The ROM **960** is read by the waveform generator **930** so that the synthesized waveform **932** is adapted to a particular monitor **360**. For example, the ROM **960** may contain calibration data of red/IR versus oxygen saturation, waveform amplitude and waveform shape information. An interface cable is described in U.S. Patent Application No. 60/117,092, referenced above. Monitor-specific SatShare™ brand interface cables are available from Masimo Corporation, Irvine, Calif. In an alternative embodiment, such as a direct connect monitor module as illustrated in FIG. **5A**, an interface cable **950** is not used and the ROM **960** may be incorporated within the monitor module **900** itself.

Plethysmograph Transmission

FIG. **10** illustrates another pulse oximetry sensor module **1000** having a sensor interface **1010**, encoder **1040**, transmitter **1050**, transmitting antenna **1070** and controller **1090**, which have the corresponding functions as those described with respect to FIG. **8**, above. The encoder **1040**, however, inputs a plethysmograph signal **1014** rather than oxygen saturation and pulse rate measurements **832** (FIG. **8**). Thus, the sensor module **1000** according to this embodiment encodes and transmits a plethysmograph signal **1014** to a corresponding monitor module **1100** (FIG. **11**) in contrast to derived physiological parameters, such as oxygen saturation and pulse rate. The plethysmograph signal **1014** is illustrated in FIG. **10** as being a direct output from the sensor interface **1010**. In another embodiment, the sensor module **1000** incorporates a decimation processor, not shown, after the sensor interface **1010** so as to provide a plethysmograph signal **1014** having a reduced sample rate.

FIG. **11** illustrates another pulse oximetry monitor module **1100** having a receive antenna **1170**, a receiver **1110**, a decoder **1120** and an interface cable **1150**, which have the corresponding functions as those described with respect to FIG. **9**, above. This monitor module embodiment **1100**, however, has a waveform modulator **1200** rather than a waveform generator **930** (FIG. **9**), as described above. The waveform modulator **1200** inputs a plethysmograph signal from the decoder **1120** rather than oxygen saturation and pulse rate measurements, as described with respect to FIG. **9**, above. Further, the waveform modulator **1200** provides an modulated waveform **1132** to the pulse oximeter monitor **360** rather than a synthesized waveform, as described with respect to FIG. **9**. The modulated waveform **1132** is a plethysmographic waveform modulated according to the monitor drive signal input **1134**. That is, the waveform modulator **1200** does not synthesize a waveform, but rather modifies the received plethysmograph signal **1124** to cause the monitor **360** to calculate oxygen saturation and pulse rate generally equivalent (within clinical significance) to that derivable by a compatible, calibrated pulse oximeter directly from the sensor signal **1012** (FIG. **10**). The waveform modulator **1200** is described in further detail with respect to FIG. **12**, below.

FIG. **12** shows a waveform modulator **1200** having a demodulator **1210**, a red digital-to-analog converter (DAC) **1220**, an IR DAC **1230**, a red amplifier **1240**, an IR amplifier **1250**, a modulator **1260**, a modulator control **1270**, a look-up table (LUT) **1280** and a ratio calculator **1290**. The waveform modulator **1200** demodulates red and IR plethysmographs ("pleths") from the decoder output **1124** into a separate red pleth **1222** and IR pleth **1232**. The waveform modulator **1200** also adjusts the amplitudes of the pleths **1222**, **1232** according to stored calibration curves for the sensor **310** (FIG. **10**) and the monitor **360** (FIG. **11**). Further, the waveform modulator **1200** re-modulates the adjusted red pleth **1242** and adjusted IR pleth **1252**, generating a modulated waveform **1132** to the monitor **360** (FIG. **11**).

As shown in FIG. **12**, the demodulator **1210** performs the demodulation function described above, generating digital red and IR pleth signals **1212**, **1214**. The DACs **1220**, **1230** convert the digital pleth signals **1212**, **1214** to corresponding analog pleth signals **1222**, **1232**. The amplifiers **1240**, **1250** have variable gain control inputs **1262**, **1264** and perform the amplitude adjustment function described above, generating adjusted red and IR pleth signals **1242**, **1252**. The modulator **1260** performs the re-modulation function described above, combining the adjusted red and IR pleth signals **1242**, **1252** according to a control signal **1272**. The

modulator control **1270** generates the control signal **1272** synchronously with the LED drive signal(s) **1134** from the monitor **360**.

Also shown in FIG. **12**, the ratio calculator **1290** derives a red/IR ratio from the demodulator outputs **1212**, **1214**. The LUT **1280** stores empirical calibration data for the sensor **310** (FIG. **10**). The LUT **1280** also downloads monitor-specific calibration data from the ROM **1160** (FIG. **11**) via the ROM output **1158**. From this calibration data, the LUT **1280** determines a desired red/IR ratio for the modulated waveform **1132** and generates red and IR gain outputs **1262**, **1264** to the corresponding amplifiers **1240**, **1250**, accordingly. A desired red/IR ratio is one that allows the monitor **360** (FIG. **11**) to derive oxygen saturation measurements from the modulated waveform **1132** that are generally equivalent to that derivable directly from the sensor signal **1012** (FIG. **10**).

One of ordinary skill in the art will recognize that some of the signal processing functions described with respect to FIGS. **8-11** may be performed either within a sensor module or within a monitor module. Signal processing functions performed within a sensor module may advantageously reduce the transmission bandwidth to a monitor module at a cost of increased sensor module size and power consumption. Likewise, signal processing functions performed within a monitor module may reduce sensor module size and power consumption at a cost of increase transmission bandwidth.

For example, a monitor module embodiment **900** (FIG. **9**) described above receives measured pulse oximeter parameters, such as oxygen saturation and pulse rate, and generates a corresponding synthesized waveform. In that embodiment, the oxygen saturation and pulse rate computations are performed within a sensor module **800** (FIG. **8**). Another monitor module embodiment **1100** (FIG. **11**), also described above, receives a plethysmograph waveform and generates a remodulated waveform. In that embodiment, minimal signal processing is performed within a sensor module **1000** (FIG. **10**). In yet another embodiment, not shown, a sensor module transmits a plethysmograph waveform or a decimated plethysmograph waveform having a reduced sample rate. A corresponding monitor module has a signal processor, such as described with respect to FIG. **8**, in addition to a waveform generator, as described with respect to FIG. **9**. The signal processor computes pulse oximeter parameters and the waveform generator generates a corresponding synthesized waveform, as described above. In this embodiment, minimal signal processing is performed within the sensor module, and the monitor module functions are performed on the pulse oximeter parameters computed within the monitor module.

Wireless Multiple Parameter Measurements

FIGS. **13-14** illustrate a multiple parameter communications adapter. FIG. **13** illustrates a multiple parameter sensor module **1300** having sensor interfaces **1310**, one or more signal processors **1330**, a multiplexer and encoder **1340**, a transmitter **1350**, a transmitting antenna **1370** and a controller **1390**. One or more physiological sensors **1301** provide input sensor signals **1312** to the sensor module **1300**. Depending on the particular sensors **1301**, the sensor module **1300** may provide one or more drive signals **1312** to the sensors **1301** as determined by the controller **1390**. The sensor interfaces **1310** input the sensor signals **1312** and output one or more conditioned signals **1314**. The conditioned signals **1314** may be coupled to the transmitter **1350** or further processed by the signal processors **1330**. If the sensor module configuration utilizes signal processors **1330**, it derives multiple parameter signals **1332** responsive to the sensor signals **1312**, which are then coupled to the transmitter **1350**. Regardless, the transmitter **1350** inputs a baseband signal **1342** that is responsive to the sensor signals **1312**. The transmitter **1350** modulates the baseband signal **1342** with a carrier to generate a transmit signal **1354**, which is coupled to the transmit antenna **1370** and communicated to a corresponding receive antenna **1470** (FIG. **14**), as described with respect to FIG. **6**, above. Alternatively, there may be multiple baseband signals **1342**, and the transmitter **1350** may transmit on multiple frequency channels, where each channel coveys data responsive to one or more of the sensor signals **1314**.

As shown in FIG. **13**, the sensor interface **1310** conditions and digitizes the sensor signals **1312** as described for a single sensor with respect to FIG. **6**, above. The resulting conditioned signals **1314** are responsive to the sensor signals **1312**. The signal processors **1330** perform signal processing on the conditioned signals **1314** to derive parameter signals **1332**, as described for a single conditioned signal with respect to FIG. **6**, above. The parameter signals **1332** may be physiological measurements such as oxygen saturation, pulse rate, blood glucose, blood pressure, EKG, respiration rate and body temperature to name a few, or may be intermediate results from which the above-stated measurements may be calculated or derived. The multiplexer and encoder **1340** combines multiple digital word or serial bit streams into a single digital word or bit stream. The multiplexer and encoder also encodes the digital word or bit stream to generate the baseband signal **1342**, as described with respect to FIG. **6**, above.

FIG. **14** illustrates a multiple parameter monitor module **1400** having a receive antenna **1470**, a receiver **1410**, a demultiplexer and decoder **1420**, one or more waveform processors **1430** and a monitor interface **1450**. The receiver **1410** inputs and demodulates the receive signal **1412** corresponding to the transmit signal **1354** (FIG. **13**) to generate a baseband signal **1414** as described with respect to FIG. **7**, above. The demultiplexer and decoder **1420** separates the symbol streams corresponding to the multiple conditioned signals **1314** (FIG. **13**) and/or parameter signals **1332** (FIG. **13**) and translates these symbol streams into multiple decoded signals **1422**, as described for a single symbol stream with respect to FIG. **7**, above. Alternatively, multiple frequency channels are received to generate multiple baseband signals, each of which are decoded to yield multiple decoded signals **1422**. The waveform processors **1430** input the decoded signals **1422** and generate multiple constructed signals **1432**, as described for a single decoded signal with respect to FIGS. **7-12**, above. The monitor interface **1450** is configured to communicate the constructed signals **1432** to the sensor ports of a multiple parameter monitor **1401** or multiple single parameter monitors, in a manner similar to that for a single constructed signal, as described with respect to FIGS. **7-12**, above. In particular, the constructed signals **1432** are adapted to the monitor **1401** so that measurements derived by the monitor **1401** from the constructed signals **1432** are generally equivalent to measurements derivable directly from the sensor signals **1312** (FIG. **13**).

A physiological measurement communications adapter is described above with respect to wireless communications and, in particular, radio frequency communications. A sensor module and monitor module, however, may also communicate via wired communications, such as telephone, Internet or fiberoptic cable to name a few. Further, wireless communications can also utilize light frequencies, such as IR or laser to name a few.

A physiological measurement communications adapter has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only. One of ordinary skill in the art will appreciate many variations and modifications of a physiological measurement communications adapter within the scope of the claims that follow.

What is claimed is:

1. An arm mountable portable patient monitoring device configured to receive physiological information from a plurality of sensors attached to a patient at at least two different measurement sites via wired connections for on-patient monitoring of parameter measurements and wireless transmission of parameter measurements to separate monitoring devices, the portable patient monitoring device comprising:

a housing configured to be secured to an arm of a patient under measurement;

a strap mountable to a back side of the housing and configured to secure the housing to the arm of the patient;

a display positioned on a front side of the housing, the display configured to show at least one status indicator of the portable patient monitoring device and one or more parameter measurements;

a first sensor port positioned on a first side of the housing, the first side of the housing configured to face toward a hand of the arm of the patient when the housing is secured to the arm of the patient, the first sensor port configured to electrically receive a signal from a pulse oximetry sensor via a wired connection from the pulse oximetry sensor to the first sensor port, the wired connection configured to extend from the first sensor port along a path substantially perpendicular to the first side of the housing;

a second sensor port positioned on the housing and configured to receive a signal from a second sensor arrangement via a wired connection;

a third sensor port positioned on the housing configured to receive a signal from a third sensor arrangement via a wired connection;

one or more signal processing arrangements configured to:

receive the signal from the pulse oximetry sensor; and

cause to be displayed, on the display, at least measurements of oxygen saturation and pulse rate derived from the signal; and

a transmitter configured to:

wirelessly transmit information indicative of the measurements of oxygen saturation and pulse rate to a separate monitoring device configured to receive the information indicative of the measurements of oxygen saturation and pulse rate.

2. The portable patient monitoring device of claim **1**, wherein the wired connection from the pulse oximetry sensor to the first sensor port is provided at least in part via a tail of the pulse oximetry sensor.

3. The portable patient monitoring device of claim **2**, wherein the wired connection is configured to run from the first sensor port, at least part way down the arm of the patient, and to a digit of the patient to which the pulse oximetry sensor is configured to be attached.

4. The portable patient monitoring device of claim **3**, wherein the digit is a thumb of the patient.

5. The portable patient monitoring device of claim **1** further comprising:

a cable providing the wired connection from the pulse oximetry sensor to the first sensor port.

6. The portable patient monitoring device of claim **5**, wherein the cable is configured to be removably coupled to the housing via the first sensor port.

7. The portable patient monitoring device of claim **6**, wherein the cable is configured to run from the first sensor port, at least part way down the arm of the patient, and to a digit of the patient to which the pulse oximetry sensor is configured to be attached, wherein the digit is on the hand of the arm of the patient.

8. The portable patient monitoring device of claim **7**, wherein the digit is a thumb of the patient.

9. The portable patient monitoring device of claim **1**, further comprising:

a battery configured to provide power to at least the display and the first sensor port.

10. The portable patient monitoring device of claim **1**, wherein the front side of the housing comprises a single user interface.

11. The portable patient monitoring device of claim **10**, wherein the single user interface comprises the display.

12. The portable patient monitoring device of claim **11**, wherein the display is positioned centrally on the front side of the housing.

13. The portable patient monitoring device of claim **12**, wherein the display positioned on the front side of the housing is sized such that the display covers most of a length of a shortest dimension of the front side of the housing.

14. The portable patient monitoring device of claim **1**, wherein the one or more signal processing arrangements are further configured to:

receive signals from the second and third sensor arrangements; and

cause to be displayed, on the display, at least measurements of one or more additional physiological parameters based on the signals from the second and third sensor arrangements.

15. The portable patient monitoring device of claim **14**, wherein the one or more signal processing arrangements are further configured to:

receive signals from the second and third sensor arrangements; and

cause to be displayed, on the display, measurements of all of the oxygen saturation, pulse rate, and the one or more additional physiological parameters.

16. The portable patient monitoring device of claim **15**, wherein the transmitter is further configured to:

wirelessly transmit information indicative of the measurements of oxygen saturation, pulse rate, and the one or more additional physiological parameters to the separate monitoring device.

17. A method of portable patient monitoring comprising:

providing a portable patient monitoring device according to claim **1**;

attaching the strap to the arm of the patient;

mounting the housing to the strap such that the first sensor port positioned on a first side of the housing faces toward the hand of the arm of the patient;

wrapping the pulse oximetry sensor around a digit of the hand of the patient;

attaching the wired connection from the pulse oximetry sensor to the first sensor port positioned on the first side of the housing; and

activating the portable patient monitoring device such that measurements of oxygen saturation and pulse rate are both:

displayed on the display of the portable patient monitoring device on the patient; and

wirelessly transmitted to the separate monitoring device configured to receive the measurements of oxygen saturation and pulse rate.

18. The method of claim **17**, further comprising:

attaching the second sensor arrangement to a second measurement site on the patient different from the hand of the patient;

attaching the wired connection from the second sensor arrangement to the second sensor port;

attaching the third sensor arrangement to a third measurement site on the patient different from both the hand of the patient and the second measurement site; and

attaching the wired connection from the third sensor arrangement to the third sensor port,

wherein the portable patient monitoring device is further activated such that measurements of one or more additional physiological parameters are both:

displayed on the display of the portable patient monitoring device on the patient; and

wirelessly transmitted to the separate monitoring device.

19. An arm mountable portable patient monitoring device configured to receive physiological information from a plurality of sensors attached to a patient at at least two different measurement sites via wired connections for on-patient monitoring of parameter measurements and wireless transmission of parameter measurements to separate monitoring devices, the portable patient monitoring device comprising:

a housing configured to be secured to an arm of a patient under measurement, the housing comprising a front side including a single user interface, the single user interface comprising a display configured to show at least one or more parameter measurements;

a strap mountable to a back side of the housing and configured to secure the housing to the arm of the patient;

a first sensor port positioned on a first side of the housing, the first side of the housing configured to face toward a hand of the arm of the patient when the housing is secured to the arm of the patient, the first sensor port configured to electrically receive a signal from a pulse oximetry sensor via a wired connection from the pulse oximetry sensor to the first sensor port, the signal from the pulse oximetry sensor including analog information;

a second sensor port positioned on the housing and configured to receive a signal from a second sensor arrangement via a wired connection, the signal from the second sensor arrangement including digital information;

a third sensor port positioned on the housing configured to receive a signal from a third sensor arrangement via a wired connection;

one or more signal processing arrangements configured to:

receive the signal from the pulse oximetry sensor including the analog information;

receive the signal from the second sensor arrangement including the digital information;

determine digital transmit information based at least in part on: the analog information included in the signal from the pulse oximetry sensor, and the digital information included in the signal from the second sensor arrangement; and

cause to be displayed, on the display, at least measurements of oxygen saturation and pulse rate derived from the signal from the pulse oximetry sensor; and

a transmitter configured to:

wirelessly transmit the digital transmit information to a separate monitoring device configured to receive the digital transmit information, wherein the digital transmit information includes at least measurements of oxygen saturation and pulse rate derived from the signal from the pulse oximetry sensor, and wherein the digital transmit information further includes at least physiological measurements derived from the signal from the second sensor arrangement.

20. The portable patient monitoring device of claim **19**, wherein the display is positioned centrally on the front side of the housing and sized such that, if measured along a shortest dimension of the front side of the housing, the display comprises most of a length of the shortest dimension.

21. A method of portable patient monitoring comprising:

providing a portable patient monitoring device according to claim **19**;

attaching the housing to the arm of the patient via the strap such that the first sensor port positioned on a first side of the housing faces toward the hand of the arm of the patient;

attaching the pulse oximetry sensor to a digit of the hand of the patient;

attaching the second sensor arrangement to the patient;

attaching the wired connection from the pulse oximetry sensor to the first sensor port positioned on the first side of the housing;

attaching the wired connection from the second sensor arrangement to the second sensor port; and

activating the portable patient monitoring device such that measurements of oxygen saturation and pulse rate are displayed on the display of the portable patient monitoring device on the patient.

22. The method of claim **21**, wherein activating the portable patient monitoring device further includes causing the digital transmit information to be wirelessly transmitted to the separate monitoring device configured to receive the digital transmit information.

* * * * *

US010255994B2

(12) **United States Patent**
Sampath et al.

(10) **Patent No.: US 10,255,994 B2**
(45) **Date of Patent: Apr. 9, 2019**

(54) **PHYSIOLOGICAL PARAMETER ALARM DELAY**

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(*) Notice: Subject to any disclaimer, the term of this patent is extended or adjusted under 35 U.S.C. 154(b) by 0 days.

(21) Appl. No.: **15/894,393**

(22) Filed: **Feb. 12, 2018**

(65) **Prior Publication Data**

US 2018/0182484 A1 Jun. 28, 2018

Related U.S. Application Data

(60) Continuation of application No. 14/975,564, filed on Dec. 18, 2015, which is a division of application No. (Continued)

(51) **Int. Cl.**

G16H 40/40	(2018.01)
G06F 3/0482	(2013.01)
G16H 40/20	(2018.01)
G16H 10/60	(2018.01)
G16H 40/63	(2018.01)

(Continued)

(52) **U.S. Cl.**
CPC ***G16H 40/40*** (2018.01); ***G06F 3/0482*** (2013.01); ***G06F 19/00*** (2013.01); ***G06F 19/3418*** (2013.01); ***G16H 10/60*** (2018.01); ***G16H 40/00*** (2018.01); ***G16H 40/20*** (2018.01); ***G16H 40/63*** (2018.01)

(58) **Field of Classification Search**
CPC .. G06F 19/322; G06F 19/327; G06F 19/3406; G06F 19/3418; G06F 3/0482
USPC 600/309–310, 320–328, 344, 353
See application file for complete search history.

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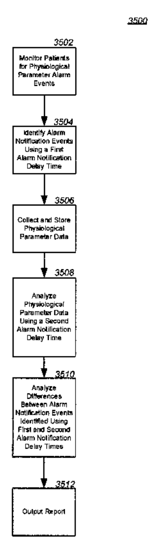
(57) **ABSTRACT**

A system configured to reduce a frequency of alarms from a physiological monitoring system including a physiological sensor configured to detect signals representative of a physiological condition of a patient and a processor configured to receive the detected signals, determine a physiological parameter of the patient, detect an alarm condition and delay a notification of the alarm condition until a predetermined alarm delay period has elapsed.

8 Claims, 56 Drawing Sheets



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(60) Provisional application No. 61/209,147, filed on Mar. 4, 2009, provisional application No. 61/296,439, filed on Jan. 19, 2010.

(51) **Int. Cl.**

G06F 19/00 (2018.01)
G16H 40/00 (2018.01)

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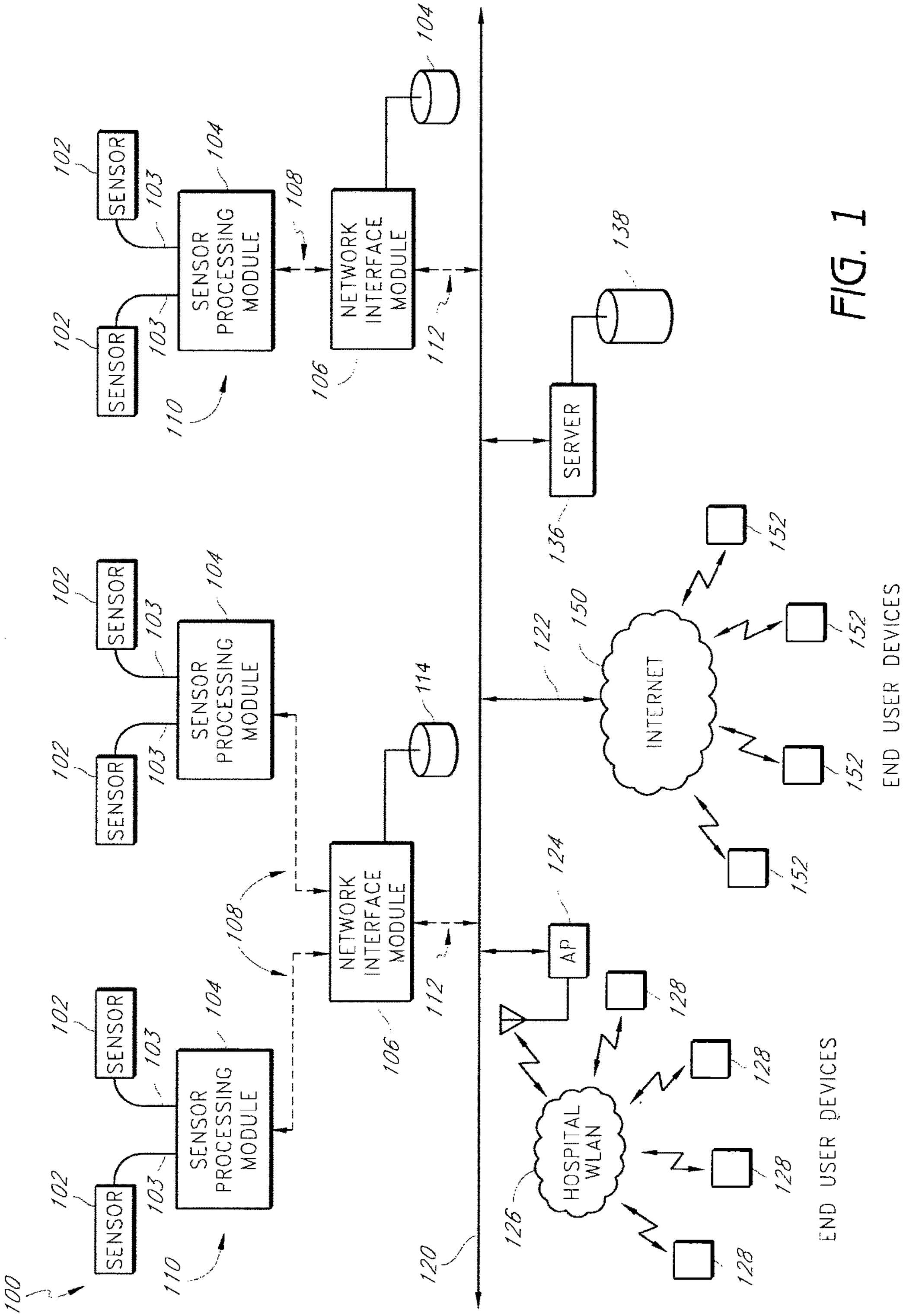

SENSOR
SENSOR PROCESSING MODULE
NETWORK INTERFACE MODULE
SERVER
INTERNET
AP
HOSPITAL WLAN
END USER DEVICES
END USER DEVICES
100
102
103
104
106
108
110
112
114
120
122
124
126
128
136
138
150
152

FIG. 1

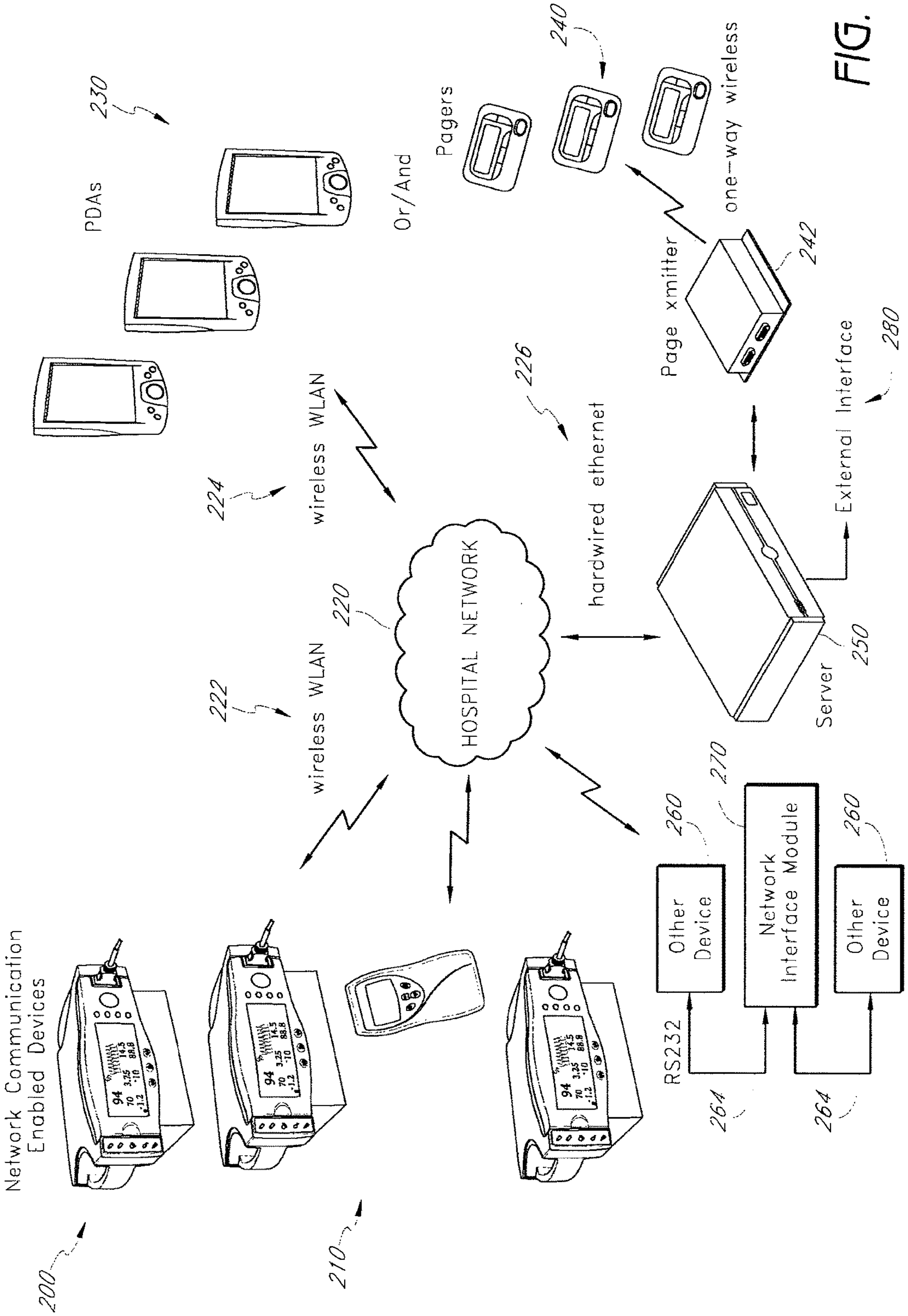

PDAs
230
Or/And
Pagers
240
one-way wireless
Page xmitter
242
wireless WLAN
224
226
hardwired ethernet
HOSPITAL NETWORK
220
External Interface
280
Server
250
wireless WLAN
222
270
260
Network Interface Module
Other Device
Other Device
RS232
264
264
Network Communication Enabled Devices
200
210

FIG. 2

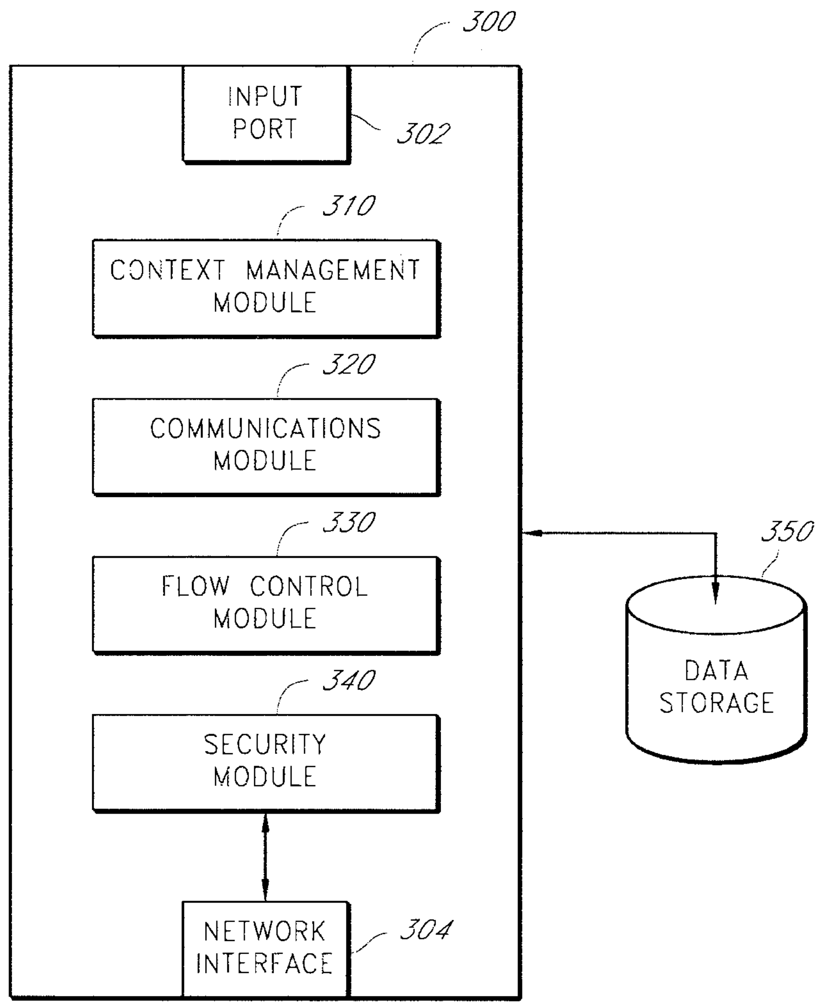

300
INPUT PORT
302
310
CONTEXT MANAGEMENT MODULE
320
COMMUNICATIONS MODULE
330
FLOW CONTROL MODULE
340
SECURITY MODULE
NETWORK INTERFACE
304
350
DATA STORAGE

FIG. 3

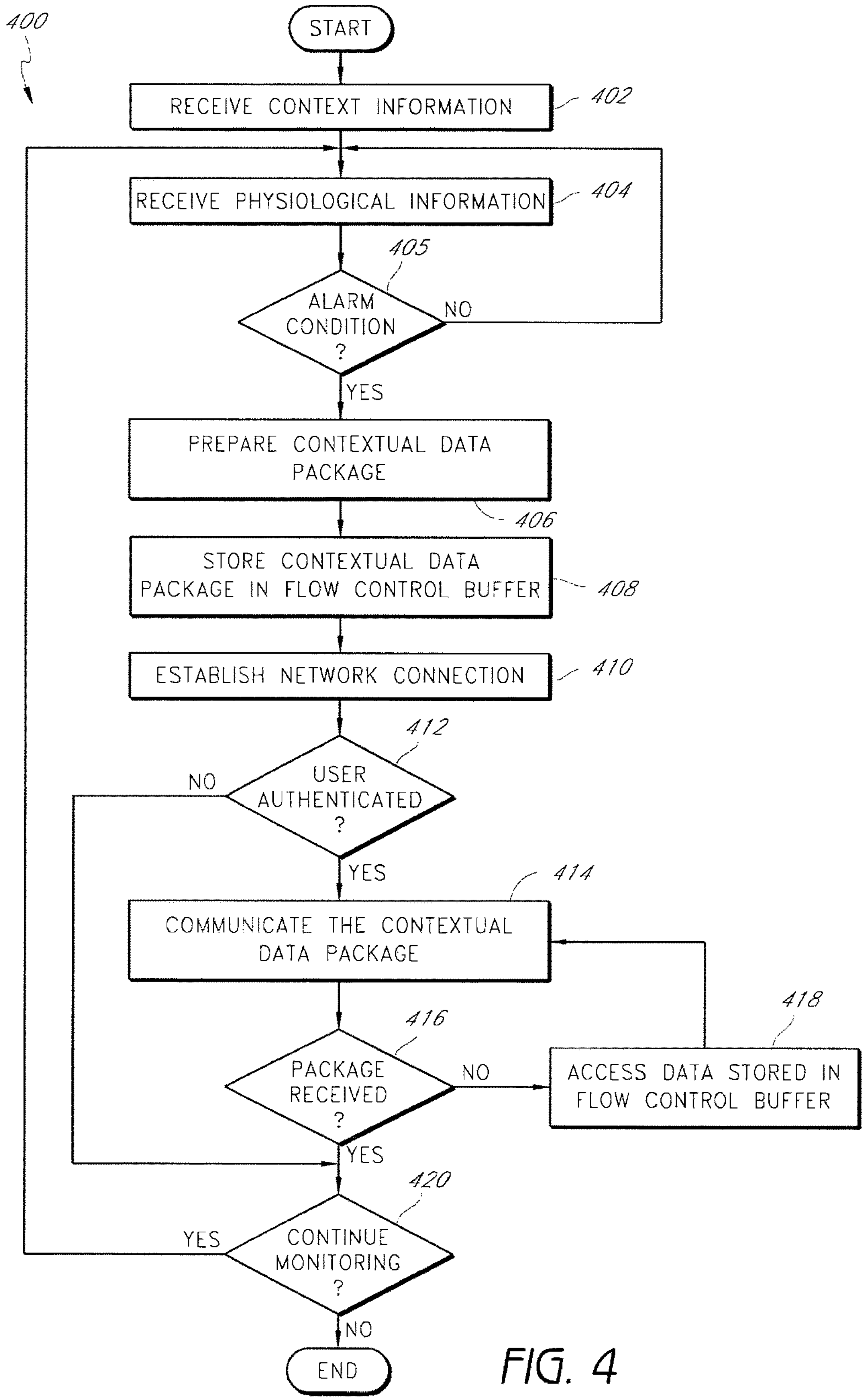

400
START
RECEIVE CONTEXT INFORMATION
402
RECEIVE PHYSIOLOGICAL INFORMATION
404
405
ALARM CONDITION ?
NO
YES
PREPARE CONTEXTUAL DATA PACKAGE
406
STORE CONTEXTUAL DATA PACKAGE IN FLOW CONTROL BUFFER
408
ESTABLISH NETWORK CONNECTION
410
412
USER AUTHENTICATED ?
NO
YES
414
COMMUNICATE THE CONTEXTUAL DATA PACKAGE
418
416
PACKAGE RECEIVED ?
NO
ACCESS DATA STORED IN FLOW CONTROL BUFFER
YES
420
YES
CONTINUE MONITORING ?
NO
END

FIG. 4

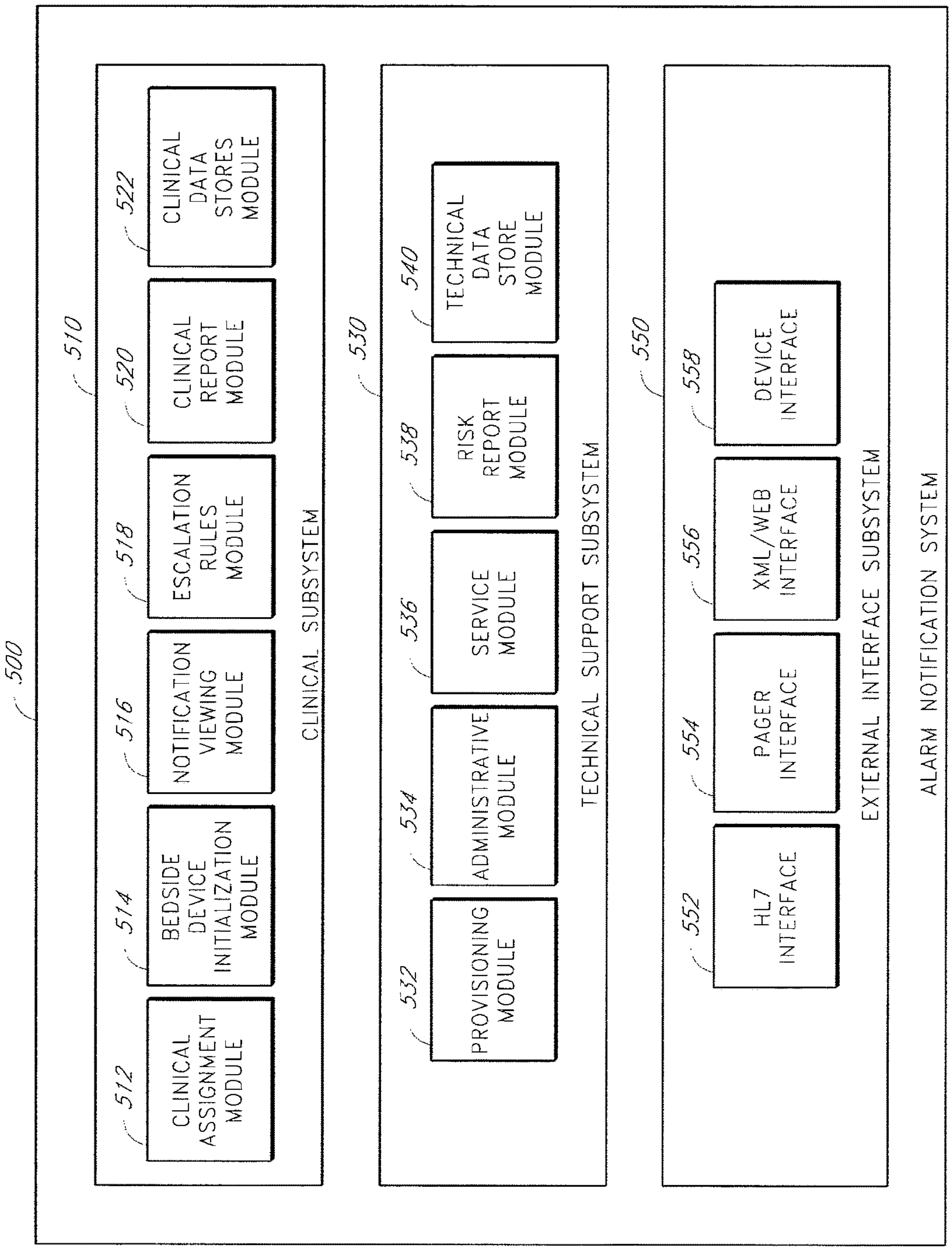

500
510
CLINICAL SUBSYSTEM
512
CLINICAL ASSIGNMENT MODULE
514
BEDSIDE DEVICE INITIALIZATION MODULE
516
NOTIFICATION VIEWING MODULE
518
ESCALATION RULES MODULE
520
CLINICAL REPORT MODULE
522
CLINICAL DATA STORES MODULE
530
TECHNICAL SUPPORT SUBSYSTEM
532
PROVISIONING MODULE
534
ADMINISTRATIVE MODULE
536
SERVICE MODULE
538
RISK REPORT MODULE
540
TECHNICAL DATA STORE MODULE
550
EXTERNAL INTERFACE SUBSYSTEM
552
HL7 INTERFACE
554
PAGER INTERFACE
556
XML/WEB INTERFACE
558
DEVICE INTERFACE
ALARM NOTIFICATION SYSTEM

FIG. 5

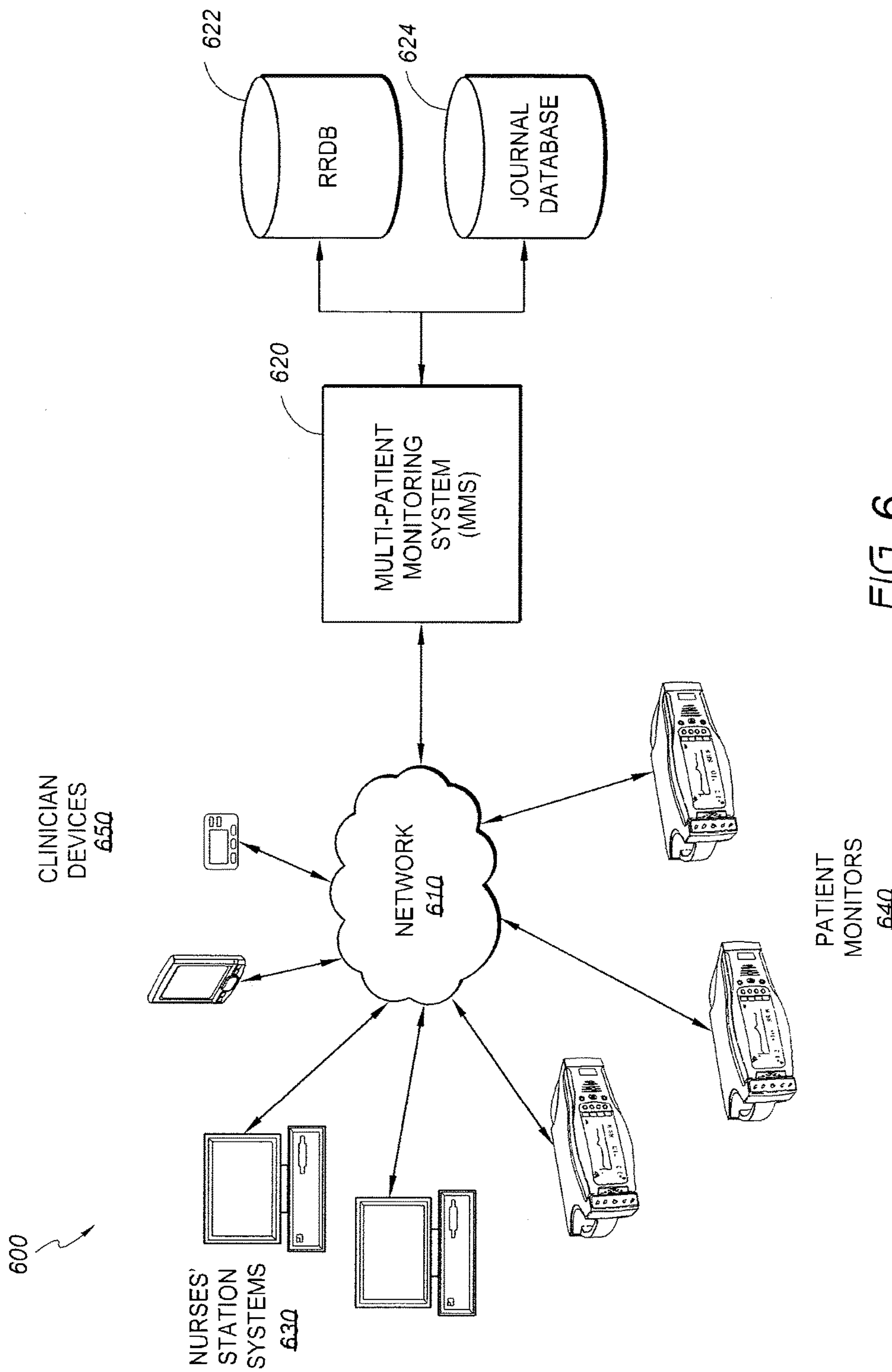

622
624
RRDB
JOURNAL DATABASE
620
MULTI-PATIENT MONITORING SYSTEM (MMS)
CLINICIAN DEVICES 650
NETWORK 610
PATIENT MONITORS 640
NURSES' STATION SYSTEMS 630
600

FIG. 6

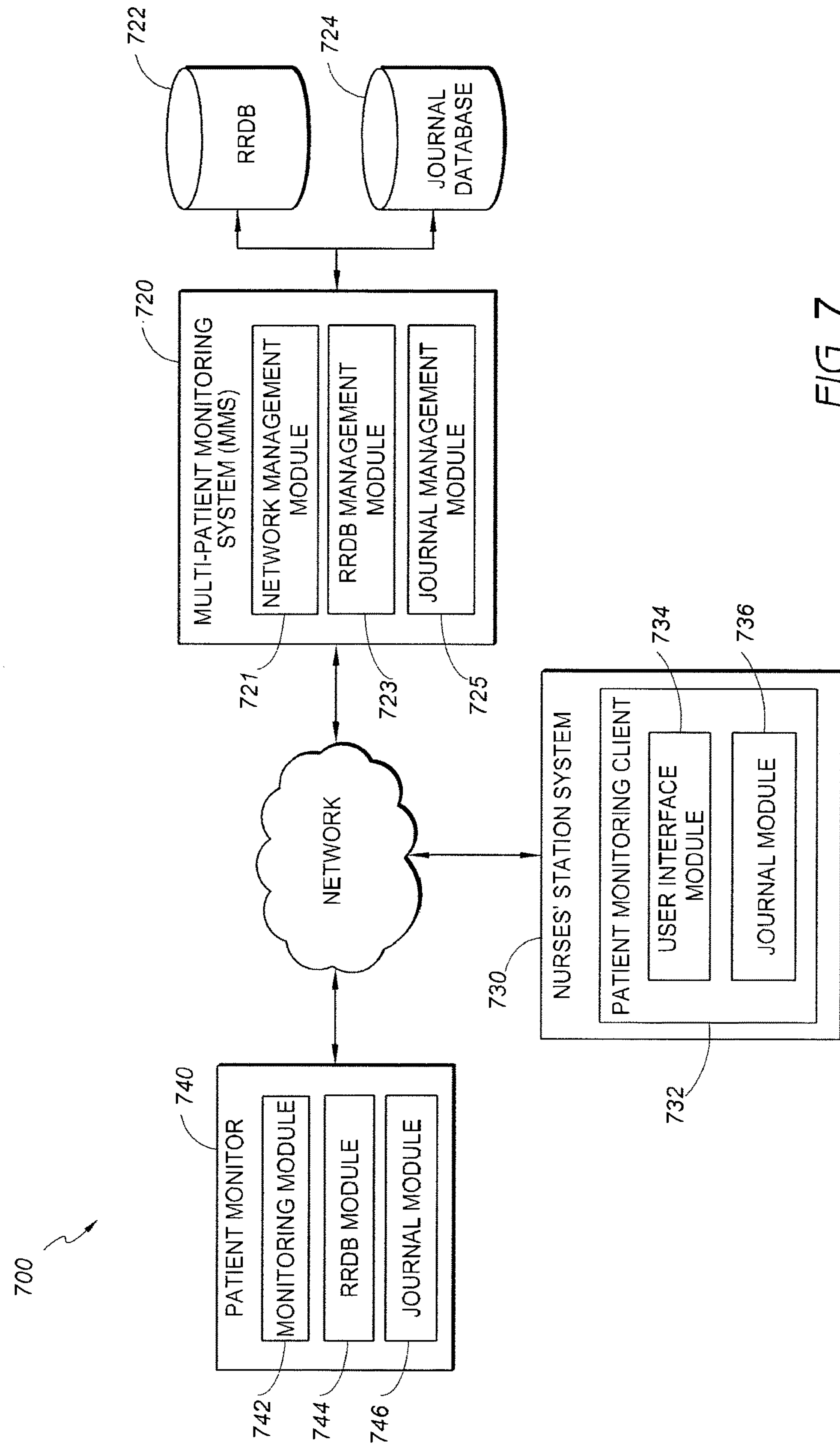
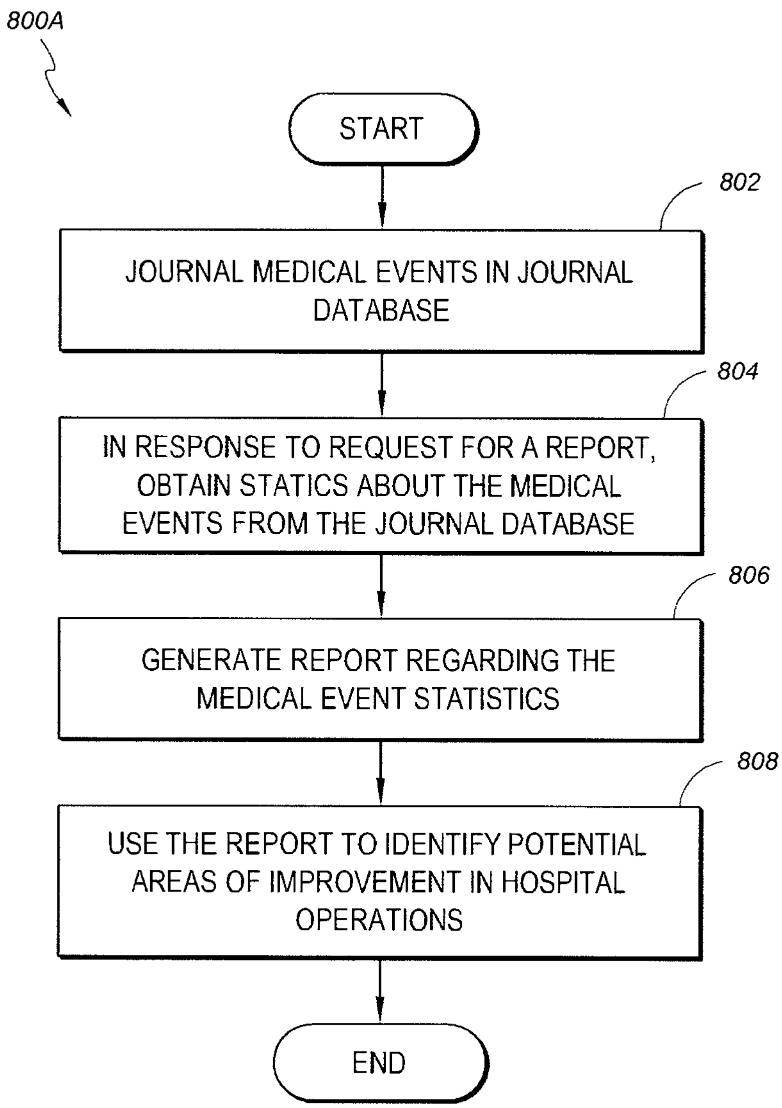
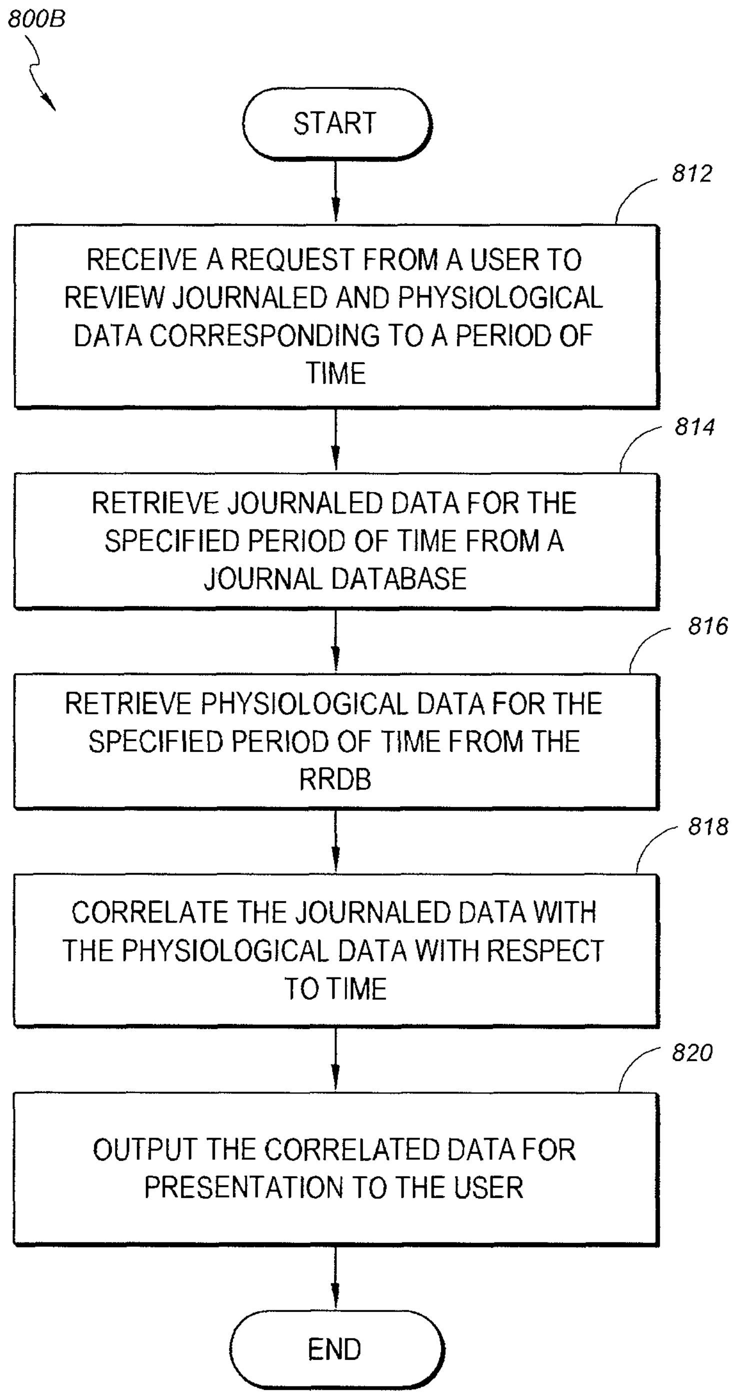

722
RRDB
724
JOURNAL DATABASE
720
MULTI-PATIENT MONITORING SYSTEM (MMS)
NETWORK MANAGEMENT MODULE
RRDB MANAGEMENT MODULE
JOURNAL MANAGEMENT MODULE
721
723
725
NETWORK
734
736
NURSES' STATION SYSTEM
PATIENT MONITORING CLIENT
USER INTERFACE MODULE
JOURNAL MODULE
730
732
740
PATIENT MONITOR
MONITORING MODULE
RRDB MODULE
JOURNAL MODULE
742
744
746
700

FIG. 7



800A
START
802
JOURNAL MEDICAL EVENTS IN JOURNAL DATABASE
804
IN RESPONSE TO REQUEST FOR A REPORT, OBTAIN STATICS ABOUT THE MEDICAL EVENTS FROM THE JOURNAL DATABASE
806
GENERATE REPORT REGARDING THE MEDICAL EVENT STATISTICS
808
USE THE REPORT TO IDENTIFY POTENTIAL AREAS OF IMPROVEMENT IN HOSPITAL OPERATIONS
END

FIG. 8A



800B
START
812
RECEIVE A REQUEST FROM A USER TO REVIEW JOURNALED AND PHYSIOLOGICAL DATA CORRESPONDING TO A PERIOD OF TIME
814
RETRIEVE JOURNALED DATA FOR THE SPECIFIED PERIOD OF TIME FROM A JOURNAL DATABASE
816
RETRIEVE PHYSIOLOGICAL DATA FOR THE SPECIFIED PERIOD OF TIME FROM THE RRDB
818
CORRELATE THE JOURNALED DATA WITH THE PHYSIOLOGICAL DATA WITH RESPECT TO TIME
820
OUTPUT THE CORRELATED DATA FOR PRESENTATION TO THE USER
END

FIG. 8B

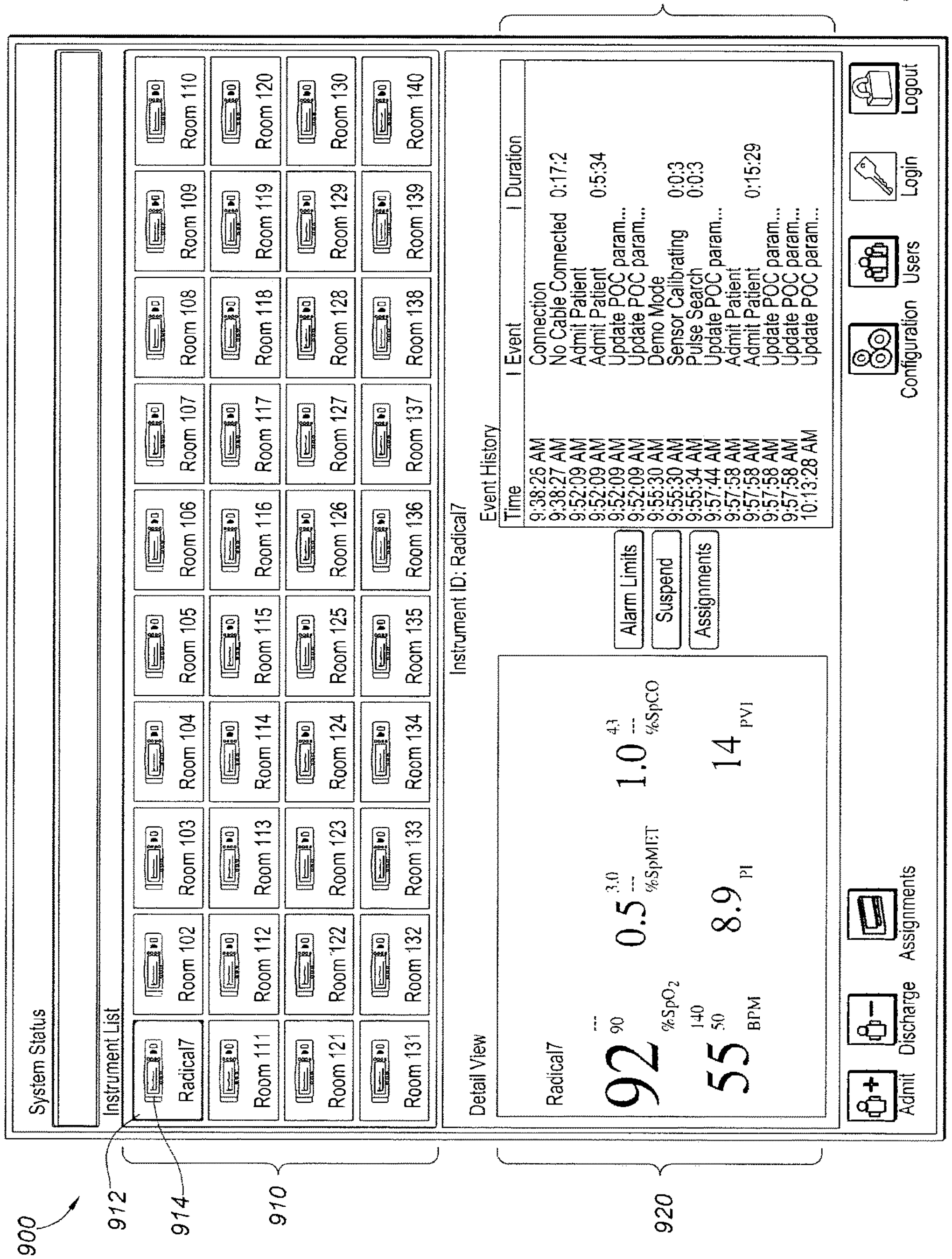

900
912
914
910
920
930
System Status
Instrument List
Radical7
Room 102
Room 103
Room 104
Room 105
Room 106
Room 107
Room 108
Room 109
Room 110
Room 111
Room 112
Room 113
Room 114
Room 115
Room 116
Room 117
Room 118
Room 119
Room 120
Room 121
Room 122
Room 123
Room 124
Room 125
Room 126
Room 127
Room 128
Room 129
Room 130
Room 131
Room 132
Room 133
Room 134
Room 135
Room 136
Room 137
Room 138
Room 139
Room 140
Detail View
Instrument ID: Radical7
Radical7
92 90 %SpO2
55 140 50 BPM
0.5 3.0 %SpMET
8.9 PI
1.0 4.3 %SpCO
14 PVI
Alarm Limits
Suspend
Assignments
Event History
Time | Event | Duration
9:38:26 AM Connection
9:38:27 AM No Cable Connected 0:17:2
9:52:09 AM Admit Patient
9:52:09 AM Admit Patient 0:5:34
9:52:09 AM Update POC param...
9:52:09 AM Update POC param...
9:55:30 AM Demo Mode
9:55:30 AM Sensor Calibrating 0:0:3
9:55:34 AM Pulse Search 0:0:3
9:57:44 AM Update POC param...
9:57:58 AM Admit Patient
9:57:58 AM Admit Patient 0:15:29
9:57:58 AM Update POC param...
9:57:58 AM Update POC param...
10:13:28 AM Update POC param...
Admit
Discharge
Assignments
Configuration
Users
Login
Logout

FIG. 9

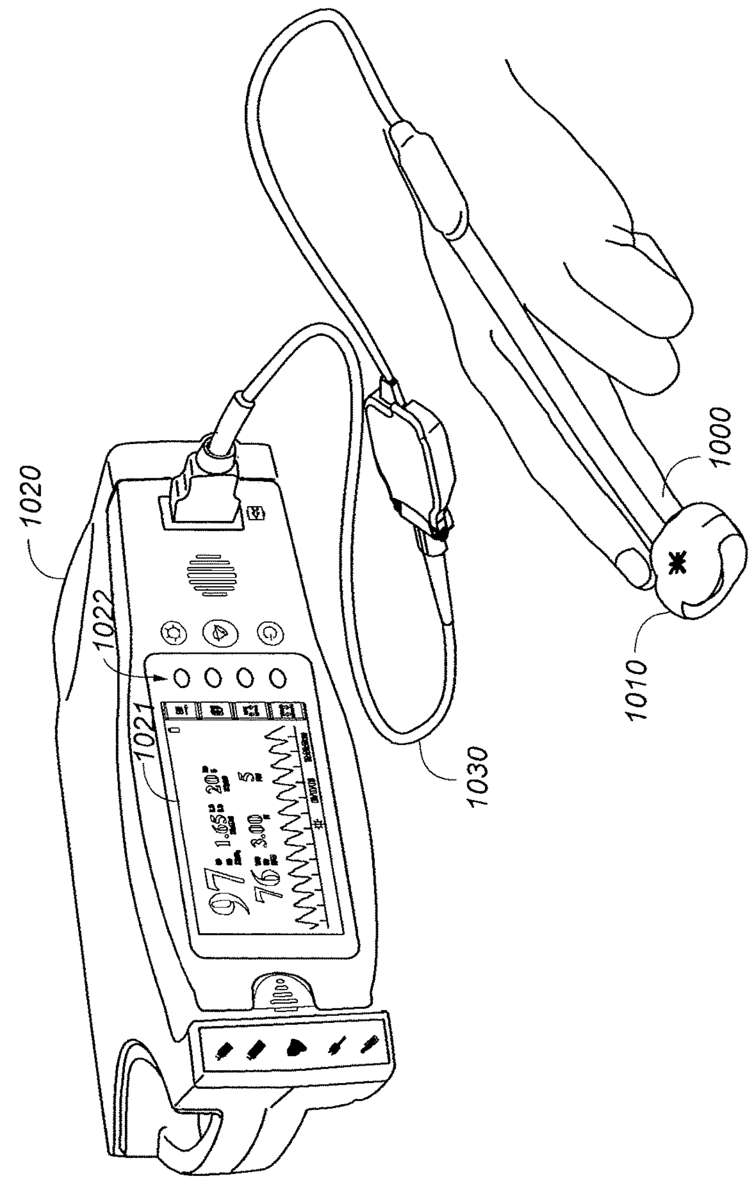


FIG 10

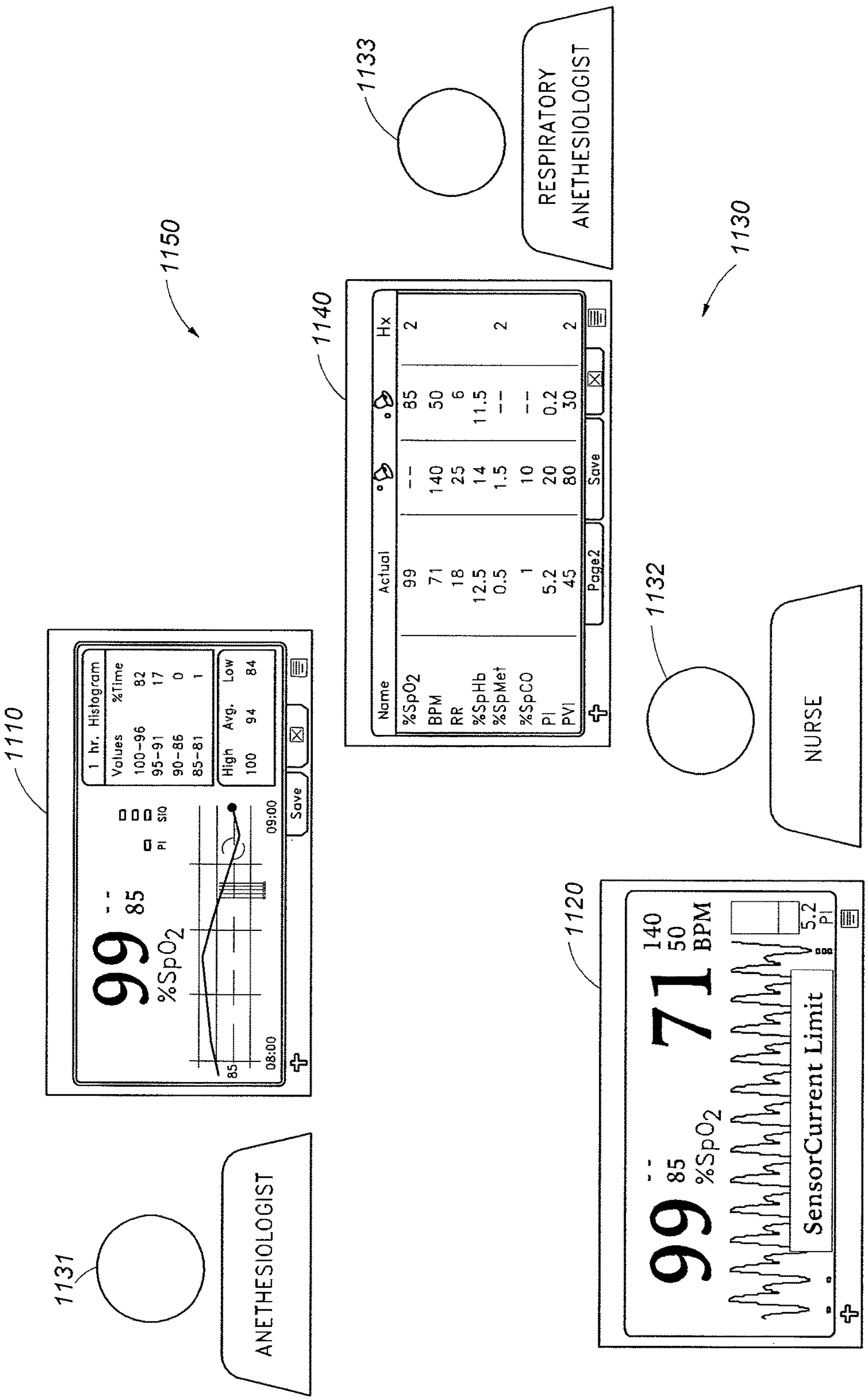

1150
1110
1120
1130
1131
1132
1133
1140
ANETHESIOLOGIST
NURSE
RESPIRATORY
ANETHESIOLOGIST
SensorCurrent Limit
%SpO2
BPM
1 hr. Histogram
Name
Actual
Hx
Save
Page2

FIG 11

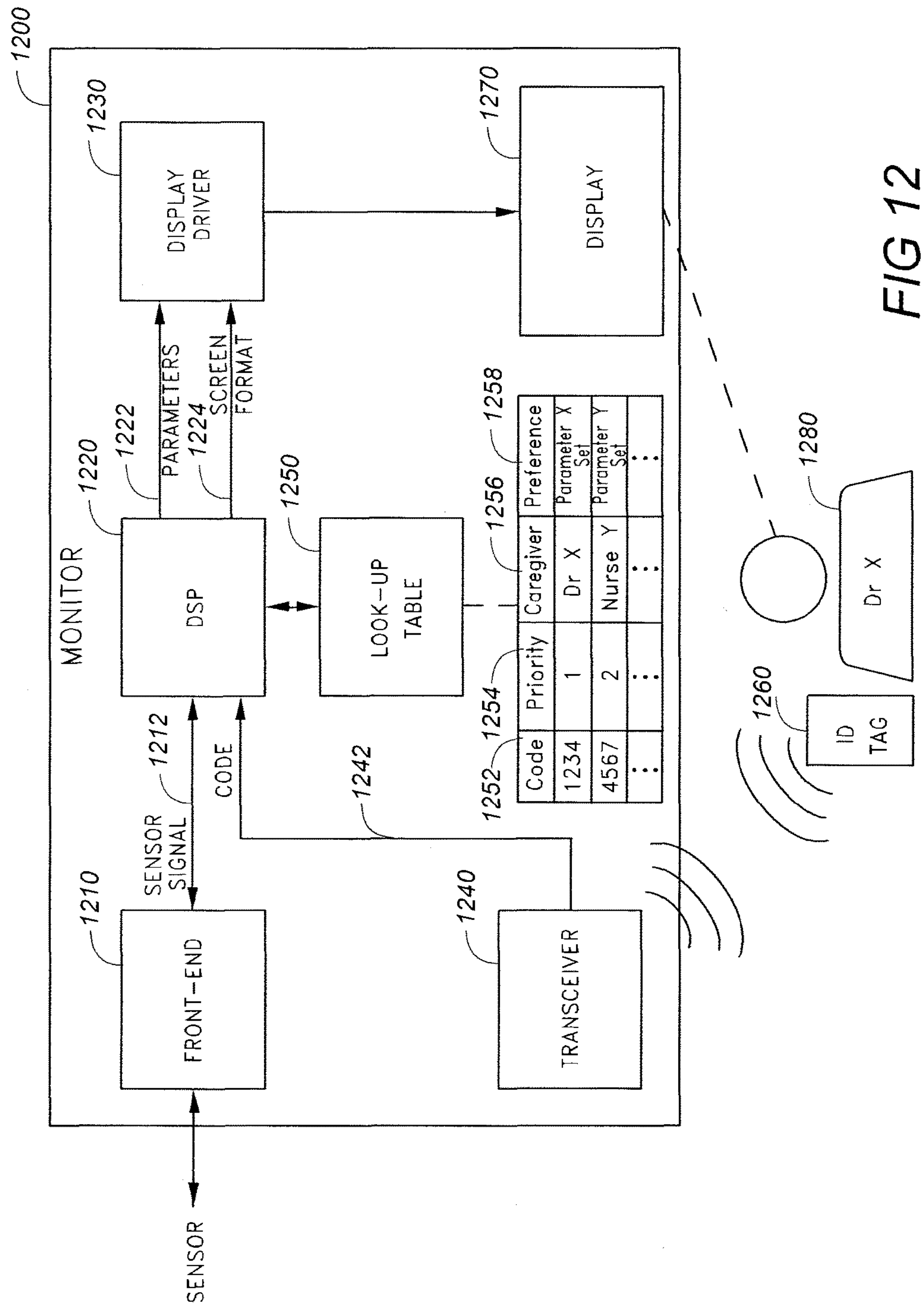

1200
MONITOR
1230
DISPLAY DRIVER
1270
DISPLAY
1220
DSP
1222
PARAMETERS
1224
SCREEN FORMAT
1250
LOOK-UP TABLE
1252
1254
1256
1258
Code
Priority
Caregiver
Preference
1234
1
Dr X
Parameter X Set
4567
2
Nurse Y
Parameter Y Set
1210
FRONT-END
1212
SENSOR SIGNAL
CODE
1240
TRANSCEIVER
1242
SENSOR
1280
Dr X
1260
ID TAG

FIG 12

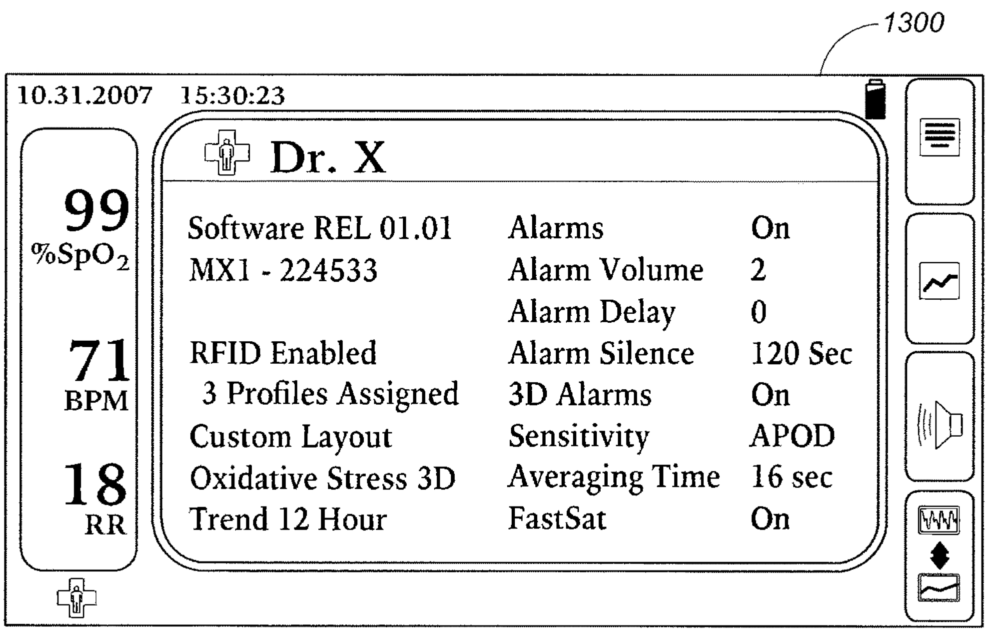

1300
10.31.2007 15:30:23
99
%SpO2
71
BPM
18
RR
Dr. X
Software REL 01.01
MX1 - 224533
RFID Enabled
3 Profiles Assigned
Custom Layout
Oxidative Stress 3D
Trend 12 Hour
Alarms On
Alarm Volume 2
Alarm Delay 0
Alarm Silence 120 Sec
3D Alarms On
Sensitivity APOD
Averaging Time 16 sec
FastSat On

FIG 13

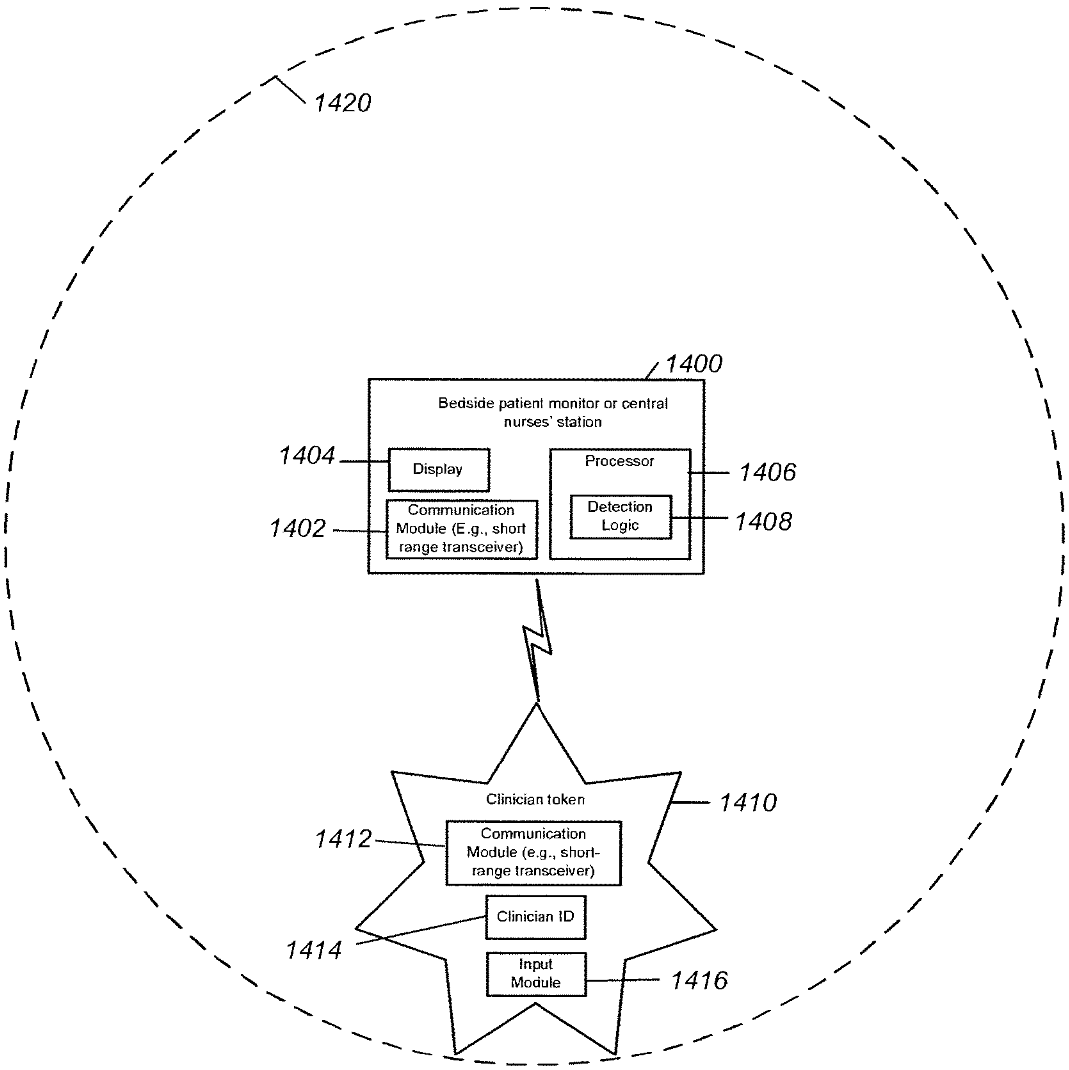

1420
1400
Bedside patient monitor or central nurses' station
1404
Display
Processor
1406
Detection Logic
1408
1402
Communication Module (E.g., short range transceiver)
Clinician token
1410
1412
Communication Module (e.g., short-range transceiver)
Clinician ID
1414
Input Module
1416

FIG 14

1500

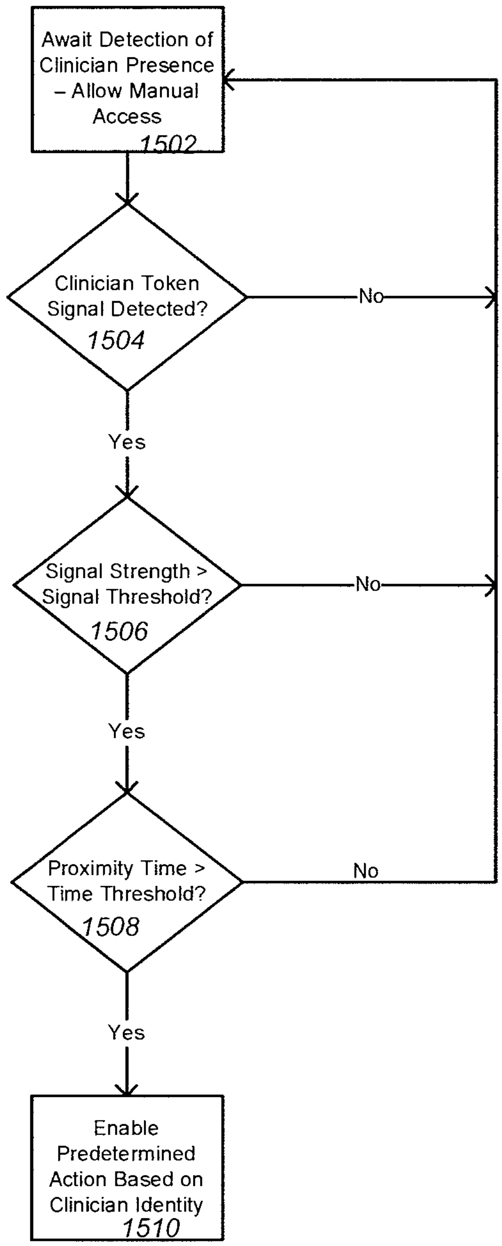

Await Detection of Clinician Presence – Allow Manual Access
1502
Clinician Token Signal Detected?
1504
No
Yes
Signal Strength > Signal Threshold?
1506
No
Yes
Proximity Time > Time Threshold?
1508
No
Yes
Enable Predetermined Action Based on Clinician Identity
1510

FIG 15

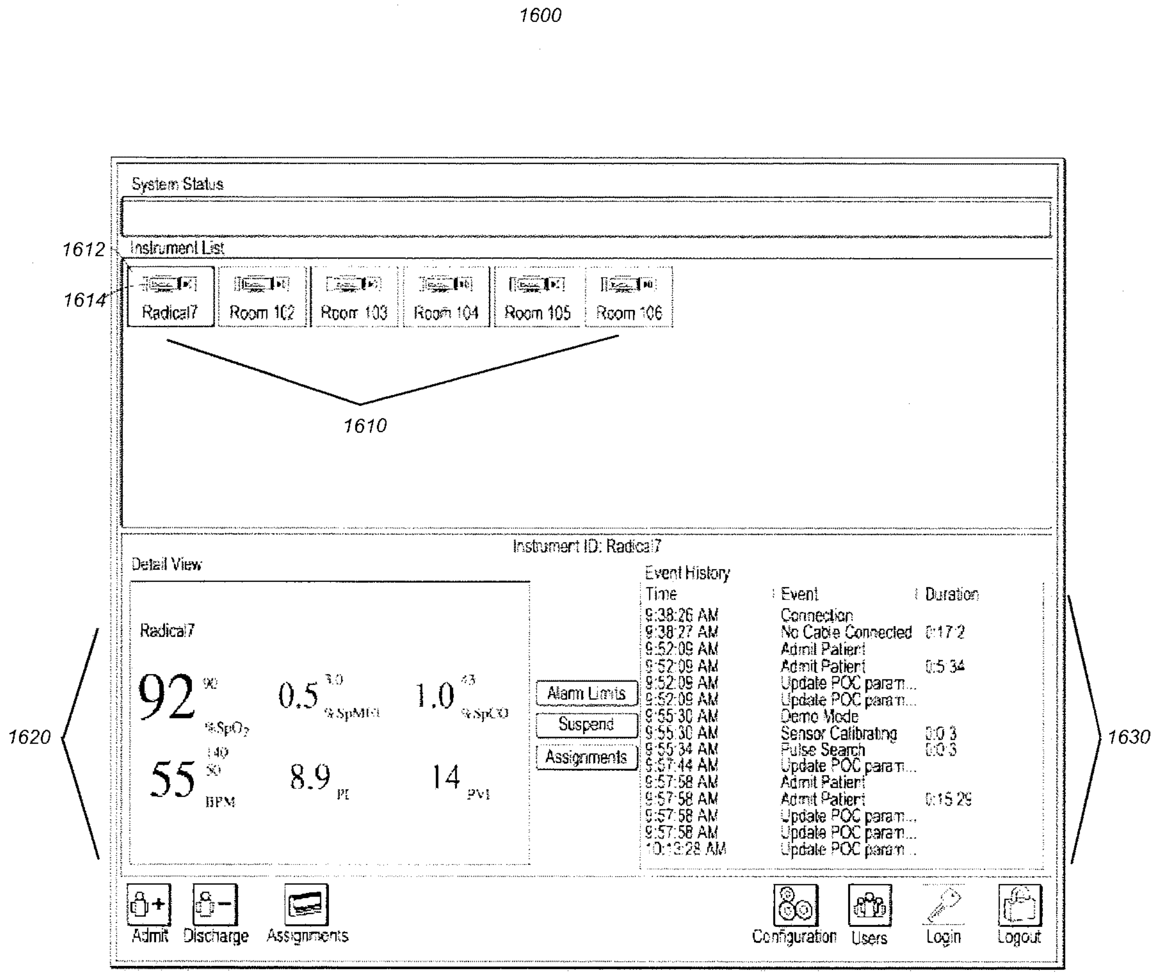

1600
System Status
Instrument List
1612
1614
Radical7
Room 102
Room 103
Room 104
Room 105
Room 106
1610
Instrument ID: Radical7
Detail View
Radical7
92
%SpO2
0.5
%SpMet
1.0
%SpCO
55
BPM
8.9
PI
14
PVI
Alarm Limits
Suspend
Assignments
Event History
Time
Event
Duration
1620
1630
Admit
Discharge
Assignments
Configuration
Users
Login
Logout

FIG 16

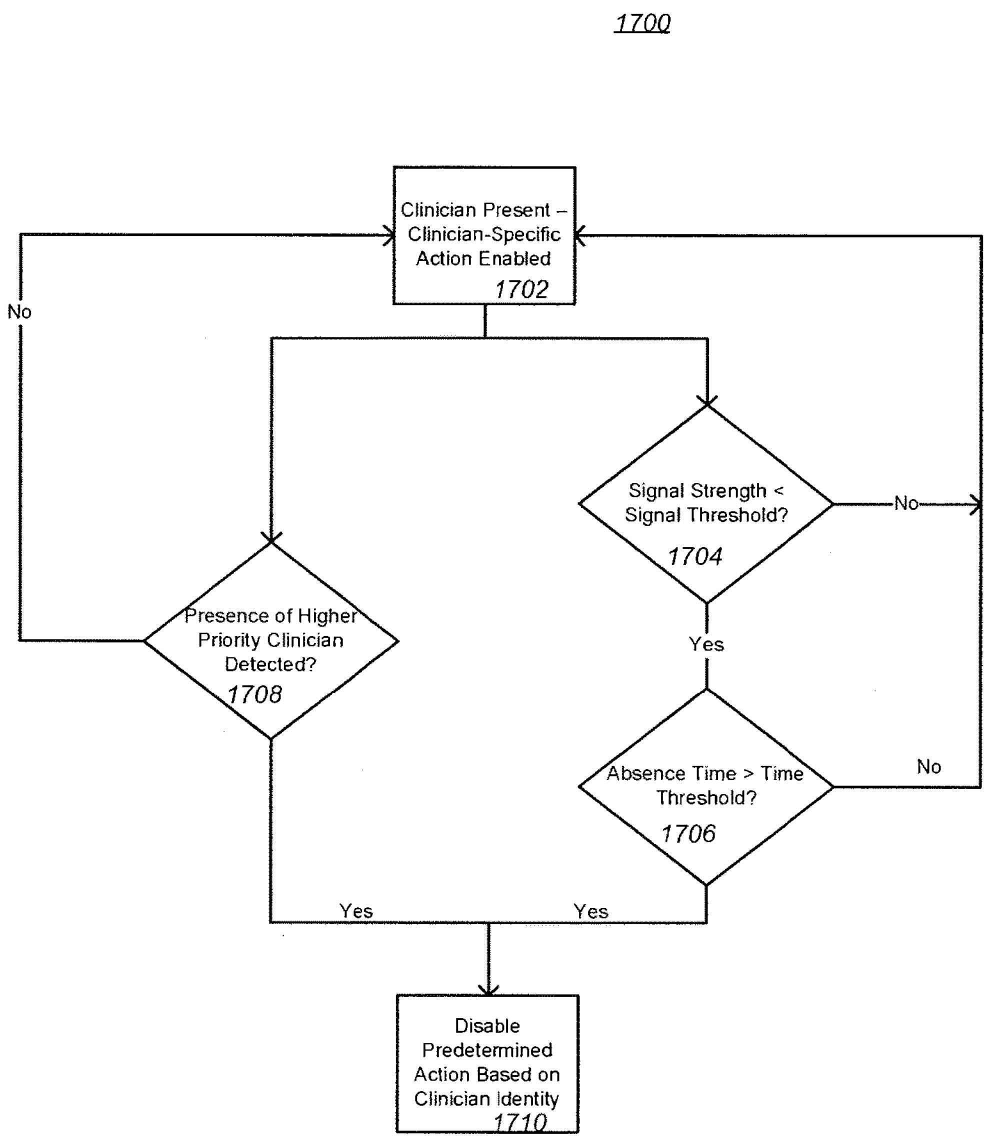

1700
Clinician Present – Clinician-Specific Action Enabled
1702
Signal Strength < Signal Threshold?
1704
No
Yes
Absence Time > Time Threshold?
1706
No
Presence of Higher Priority Clinician Detected?
1708
No
Yes
Yes
Disable Predetermined Action Based on Clinician Identity
1710

FIG 17

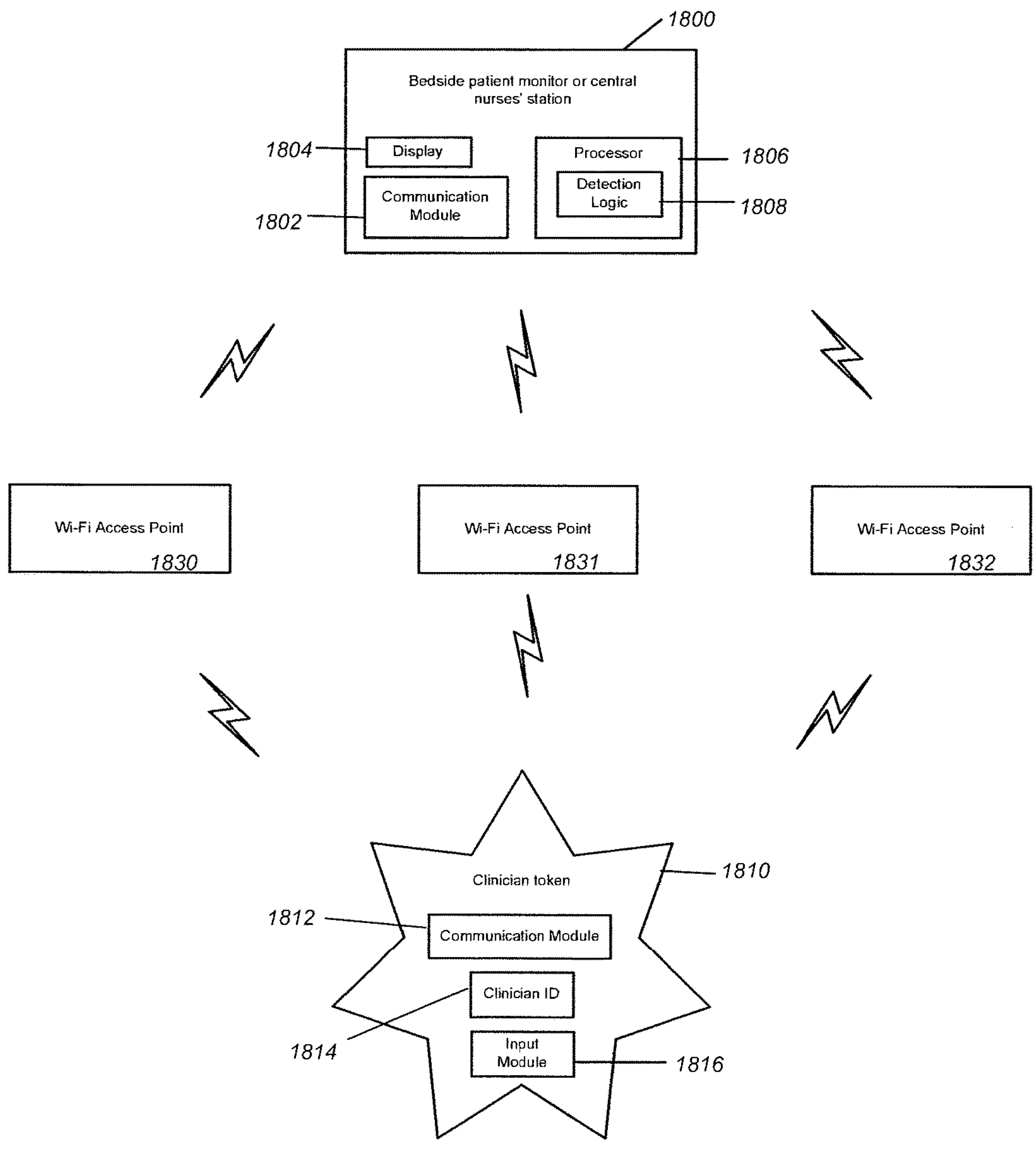

1800
Bedside patient monitor or central nurses' station
1804
Display
Processor
1806
Detection Logic
1808
Communication Module
1802
Wi-Fi Access Point
1830
Wi-Fi Access Point
1831
Wi-Fi Access Point
1832
Clinician token
1810
1812
Communication Module
Clinician ID
1814
Input Module
1816

FIG 18

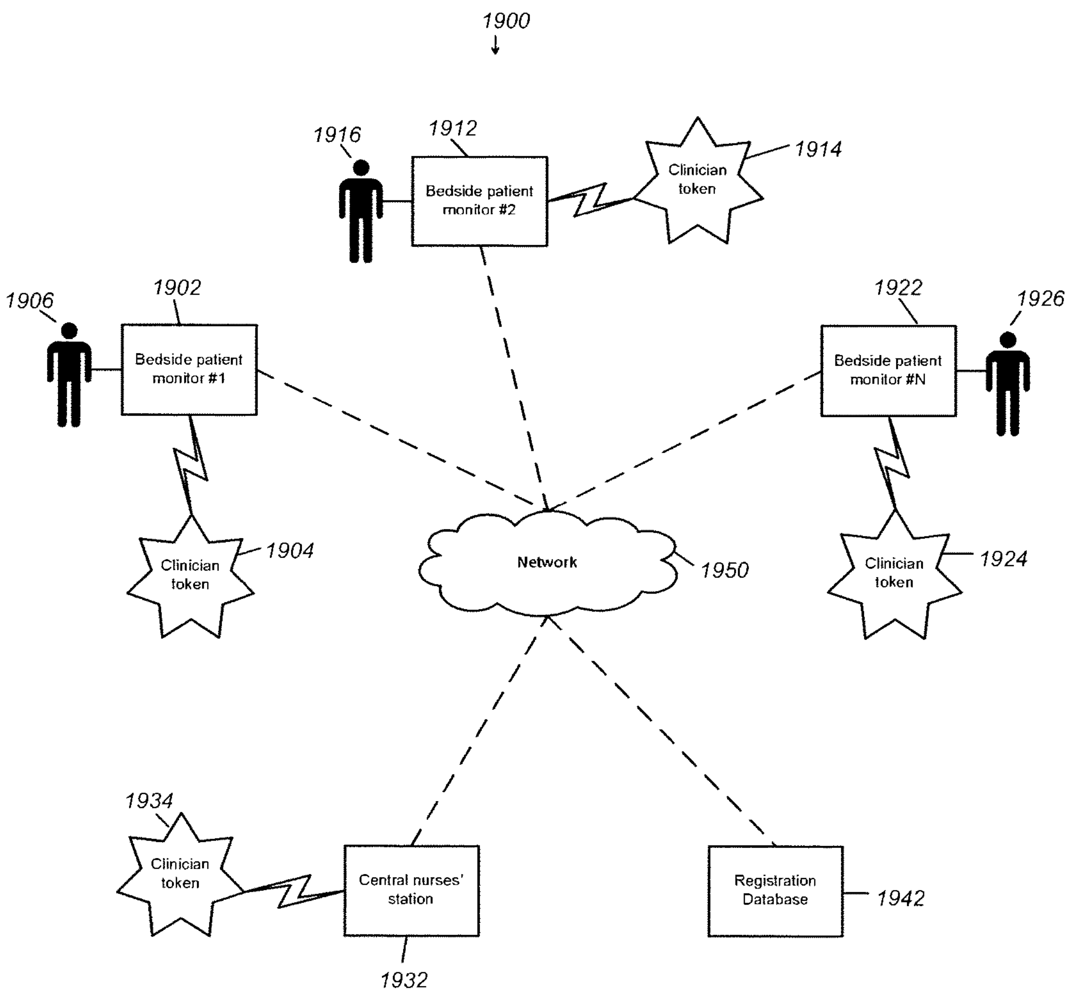

1900
1916
1912
Bedside patient monitor #2
Clinician token
1914
1906
1902
Bedside patient monitor #1
1922
1926
Bedside patient monitor #N
Clinician token
1904
Network
1950
Clinician token
1924
1934
Clinician token
Central nurses' station
Registration Database
1942
1932

FIG 19

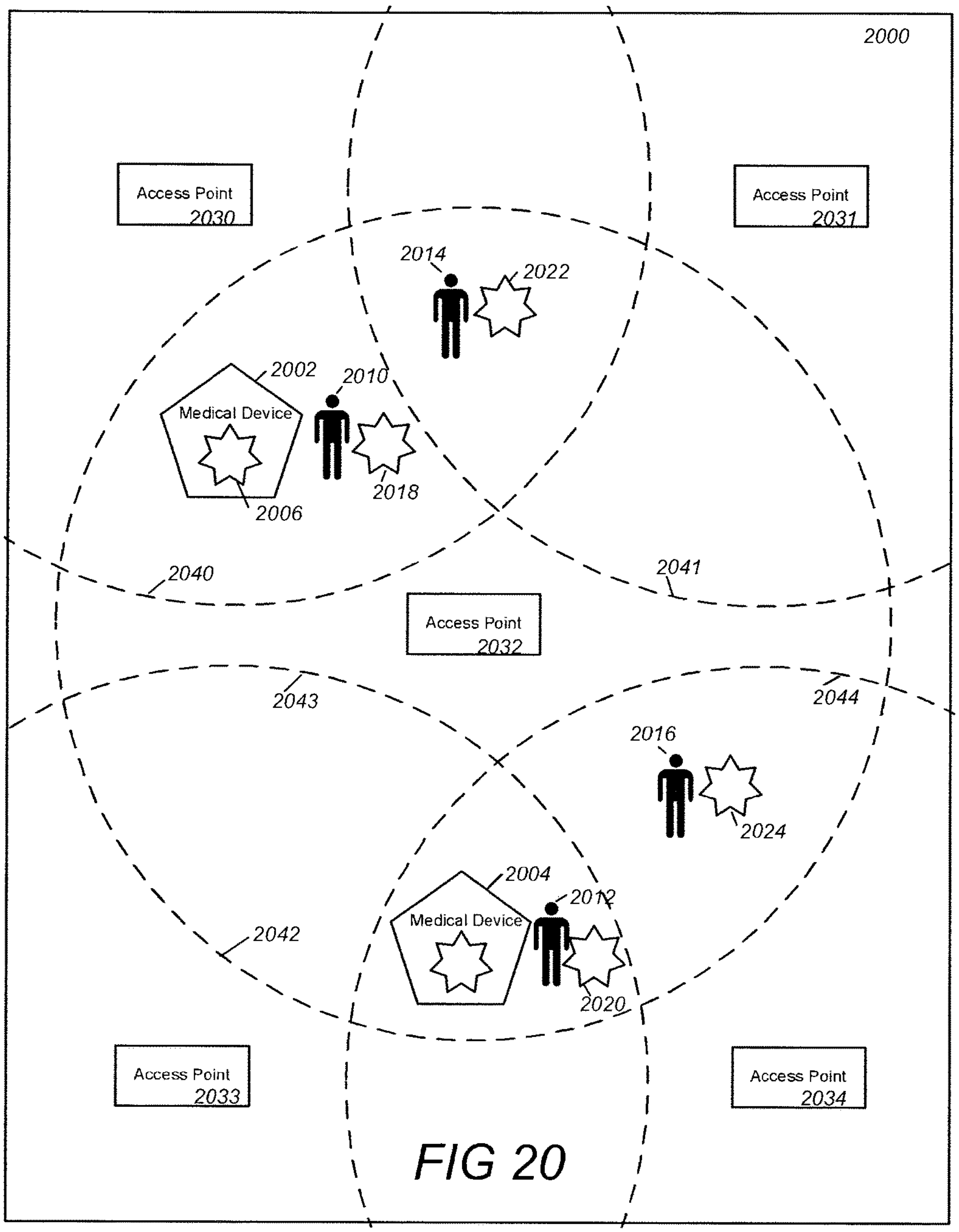

2000
Access Point
2030
Access Point
2031
2014
2022
2002
2010
Medical Device
2018
2006
2040
2041
Access Point
2032
2043
2044
2016
2024
2004
2012
Medical Device
2042
2020
Access Point
2033
Access Point
2034

FIG 20

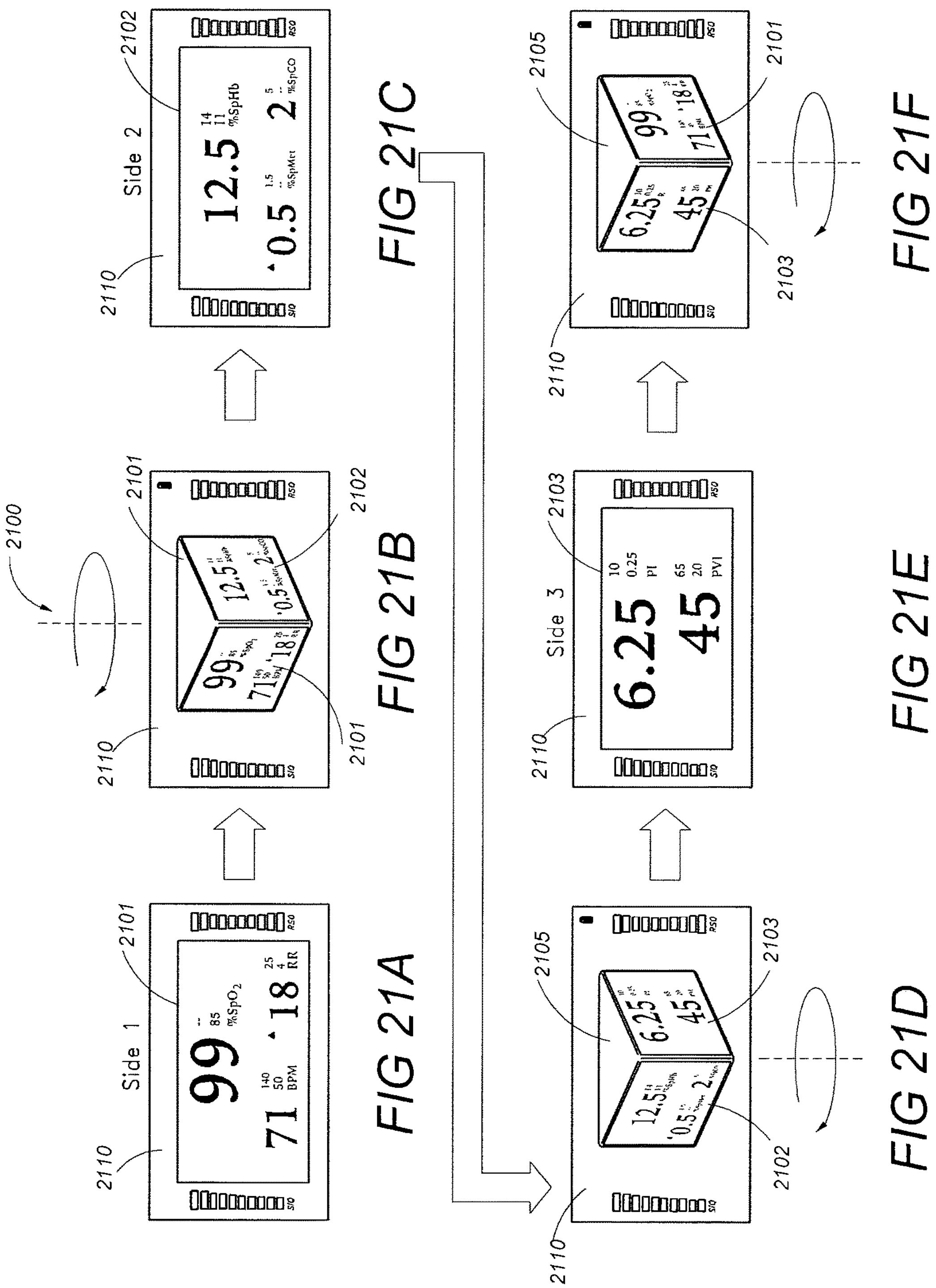


FIG 21A

FIG 21B

FIG 21C

FIG 21D

FIG 21E

FIG 21F

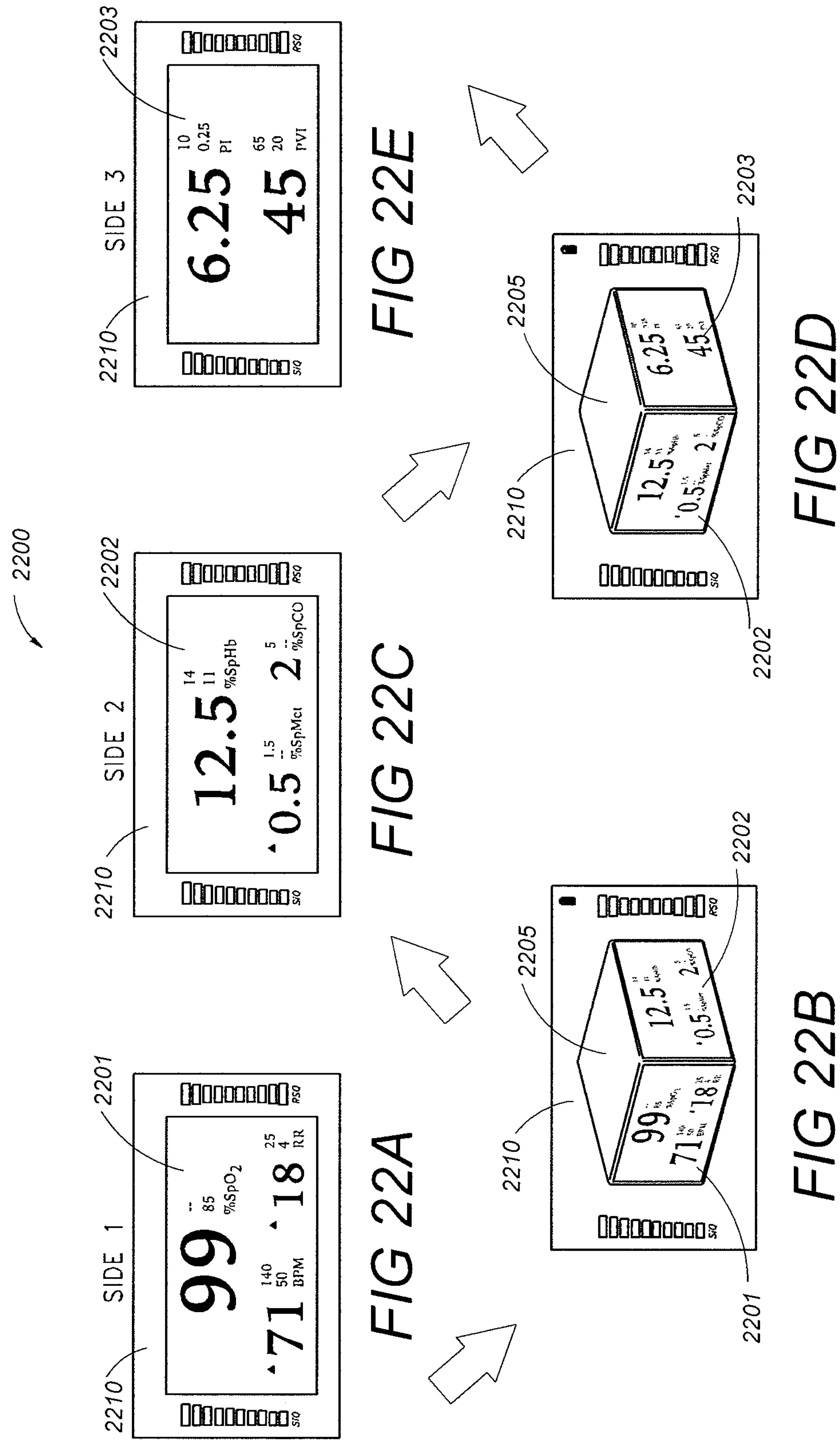


FIG 22A

FIG 22B

FIG 22C

FIG 22D

FIG 22E

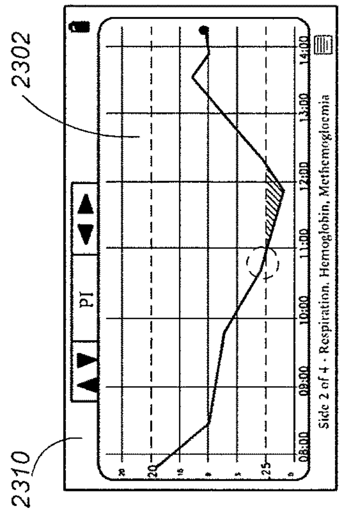


FIG 23C

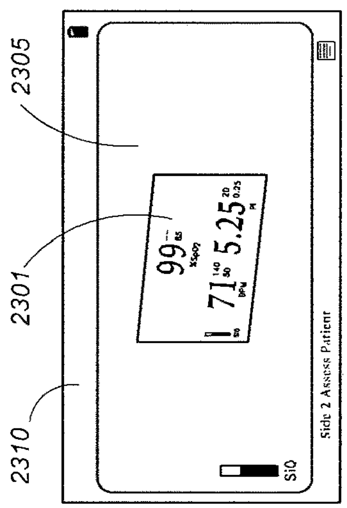


FIG 23B

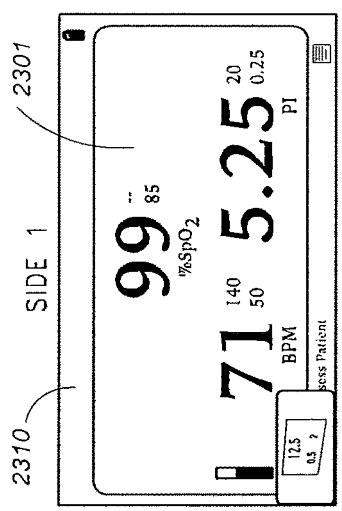


FIG 23A

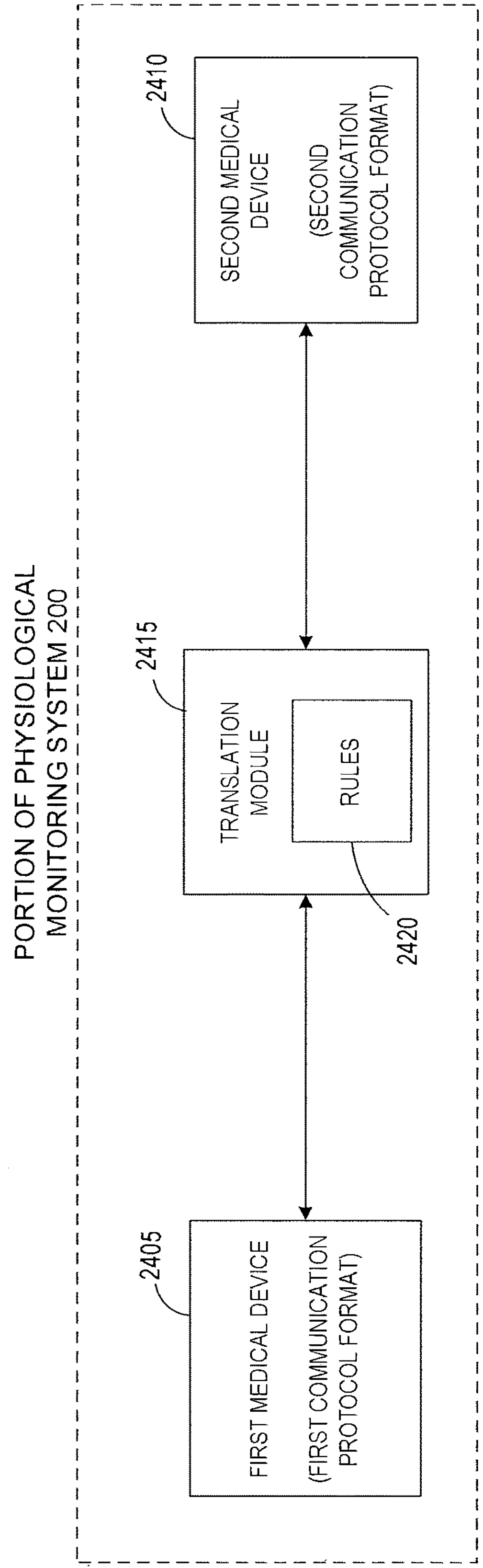

PORTION OF PHYSIOLOGICAL MONITORING SYSTEM 200
2405
FIRST MEDICAL DEVICE
(FIRST COMMUNICATION PROTOCOL FORMAT)
2415
TRANSLATION MODULE
RULES
2420
2410
SECOND MEDICAL DEVICE
(SECOND COMMUNICATION PROTOCOL FORMAT)

FIG. 24A

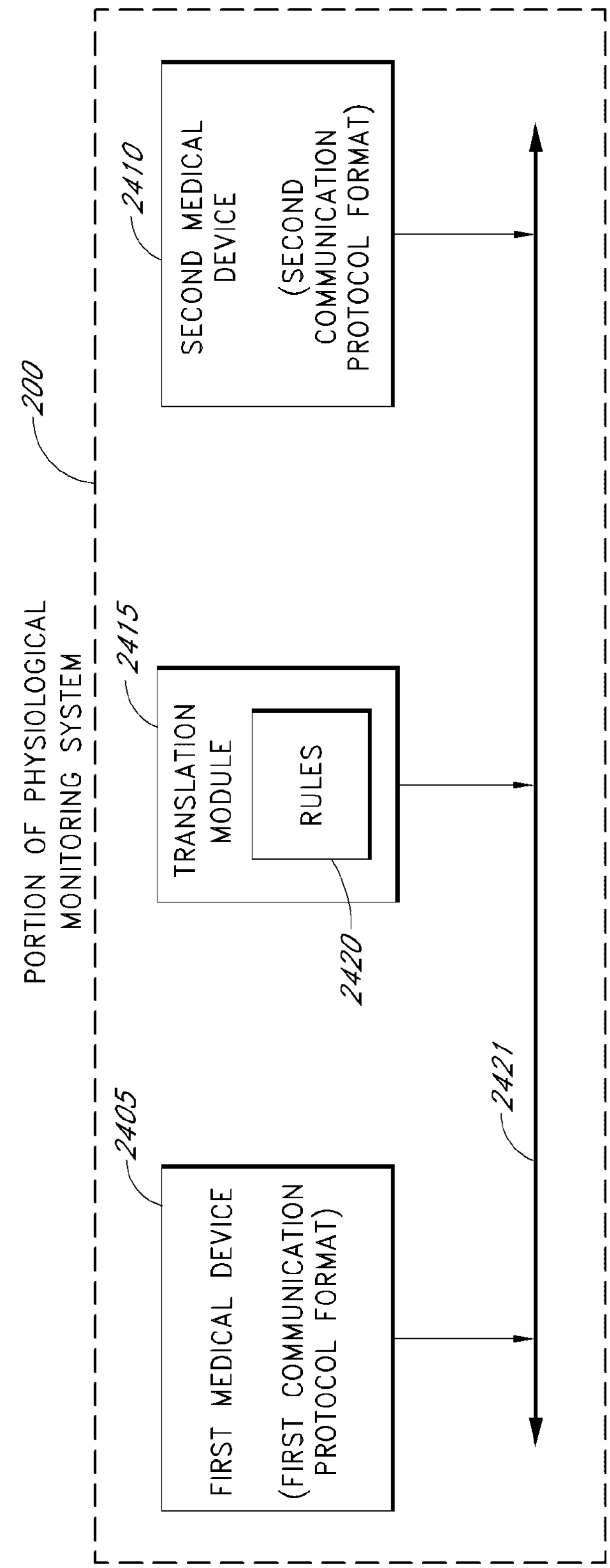

PORTION OF PHYSIOLOGICAL MONITORING SYSTEM
200
SECOND MEDICAL DEVICE (SECOND COMMUNICATION PROTOCOL FORMAT)
2410
TRANSLATION MODULE
RULES
2415
2420
FIRST MEDICAL DEVICE (FIRST COMMUNICATION PROTOCOL FORMAT)
2405
2421

FIG. 24B

2505

2506

```
<SB>
MSH^~|\&^VAFC PIMS^50^NPTF-508^200^20091120104609-0600^^ADT~A01^58103^P^^^^^^USA<CR>
EVN^A01^20091120104517-0600^^05<CR>
PID^1^500000003V302090^11~7~M10^""^LONG~BRIAN^""^19800401^M^^""~~0005~""~~CDC^""~""~""~""~""~~P~""~""|
    ""~""~""~""~""~~VACAE~""~""~~~""&""|""~""~""~""~""~~VACAA~""~""~~~""&""|""~""~""~""~""~~VACAC~""~""
    ~~~""&""|""~""~""~""~""~~VACAM~""~""~~~""&""|""~""~""~""~""~~VACAO~""~""~~~""&""^^""^""^^""^29^^""^
    ^^""~~0189~""~~CDC^ <CR>
PD1^^^SOFTWARE SERVICE~~050^""<CR>
ZPD^1^""^""^""^""^""^""^""^""^0^""^""^""^0^""^0^""^""^""<CR>
PV1^1^I^PSYCH~304~1^^^""~""~""^25~WESSELHOFT~MEAGAN^^^94^^^^^^^^NON-VETERAN
    (OTHER)^^^25^^^^^^^^^^^^^^^^^^^^^^^^20091120104517-0600^""^^^^^18<CR>
ROL^18-
    25*1^CO^""~""~""~T~""~VA01^25&50~WESSELHOFT~MEAGAN~""~""~""~""~VA200|""~""~""~""~""~""~""~SSA<CR
    >
ROL^18-
    25*2^CO^""~""~""~A~""~VA01^25&50~WESSELHOFT~MEAGAN~""~""~""~""~VA200|""~""~""~""~""~""~""~SSA<CR
    >
DG1^1^^^IBS<CR>
ZSP^1^0^""^N^""^""^""^""<CR>
ZEL^1^8^--~~^""^""^""^""^0^NON-VETERAN (OTHER)^""^""^""^""^""^""^""^""^""^""^""<CR>
ZCT^1^1^""^""^""^""^""^""<CR>
ZEM^1^1^""^""^""^""^""<CR>
ZIR^<CR>
ZEN^1<CR>
<EB><CR>
```

FIG. 25A

```
<?xml version="1.0" encoding="UTF-8" standalone="no" ?>
  <ev7>
    <MSH>
      <MSH.1>^</MSH.1>
      <MSH.2>~|\&amp;</MSH.2>
      <MSH.3>VAFC PIMS</MSH.3>
      <MSH.4>50</MSH.4>
      <MSH.5>NPTF-508</MSH.5>
      <MSH.6>200</MSH.6>
      <MSH.7>20091120104609-0600</MSH.7>
      <MSH.9>
        <component n="1">ADT</component>
        <component n="2">A01</component>
      </MSH.9>
      <MSH.10>58103</MSH.10>
      <MSH.11>P</MSH.11>
      <MSH.17>USA</MSH.17>
    </MSH>
    <EVN>
      <EVN.1>A01</EVN.1>
      <EVN.2>20091120104517-0600</EVN.2>
      <EVN.4>05</EVN.4>
    </EVN>
    ...
  <ev7>
```


FIG. 25B

```
<?xml version="1.0" encoding="UTF-8"?>
<ADT_A01>
  <MSH>
    <MSH.1>^</MSH.1>
    <MSH.2>~|\&amp;</MSH.2>
    <MSH.3>
      <HD.1>VAFC PIMS</HD.1>
    </MSH.3>
    <MSH.4>
      <HD.1>50</HD.1>
    </MSH.4>
    <MSH.5>
      <HD.1>NPTF-508</HD.1>
    </MSH.5>
    <MSH.6>
      <HD.1>200</HD.1>
    </MSH.6>
    <MSH.7>
      <TS.1>20091120104609-0600</TS.1>
    </MSH.7>
    <MSH.9>
      <MSG.1>ADT</MSG.1>
      <MSG.2>A01</MSG.2>
    </MSH.9>
    <MSH.10>58103</MSH.10>
    <MSH.11>
      <PT.1>P</PT.1>
    </MSH.11>
    <MSH.17>USA</MSH.17>
  </MSH>
  ...
```


FIG. 25C

2510


```
<output-message>
  <ACK>
    <MSH>
      <MSH.1>^</MSH.1>
      <MSH.2>~|\&amp;</MSH.2>
      <MSH.3>
        <HD.1>NPTF-508</HD.1>
      </MSH.3>
      <MSH.4>
        <HD.1>200</HD.1>
      </MSH.4>
      <MSH.5>
        <HD.1>VAFC PIMS</HD.1>
      </MSH.5>
      <MSH.6>
        <HD.1>50</HD.1>
      </MSH.6>
      <MSH.7>
        <TS.1>20091120104619.8053-0800</TS.1>
      </MSH.7>
      <MSH.9>
        <MSG.1>ACK</MSG.1>
        <MSG.3>ACK</MSG.3>
      </MSH.9>
      <MSH.10>856bc9bd-97c8-4aa5-b411-3cd6fe2edd86</MSH.10>...
    </MSH>
    <MSA>
      <MSA.1>AA</MSA.1>
      <MSA.2>58103</MSA.2>
    </MSA>
  </ACK>
</output-message>
```


FIG. 25D

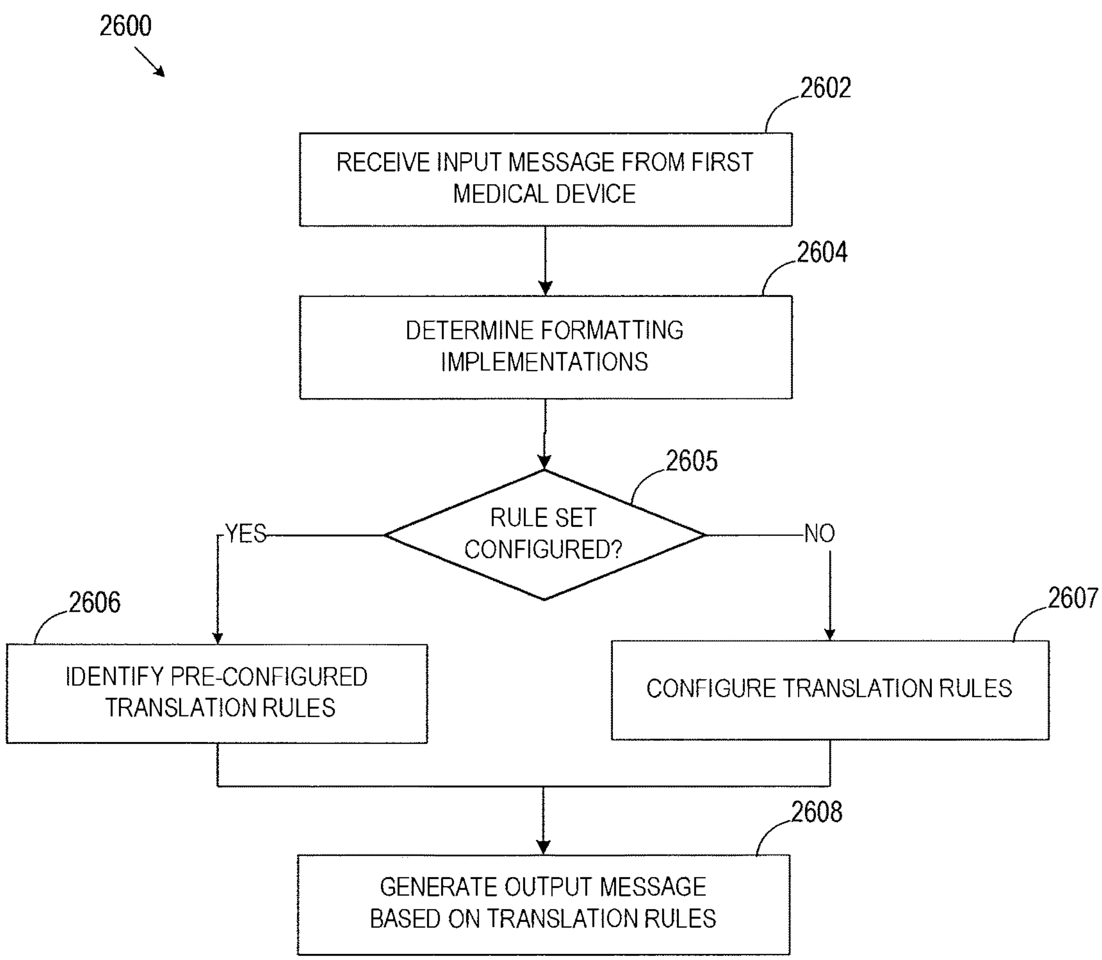

2600
2602
RECEIVE INPUT MESSAGE FROM FIRST MEDICAL DEVICE
2604
DETERMINE FORMATTING IMPLEMENTATIONS
2605
RULE SET CONFIGURED?
YES
NO
2606
IDENTIFY PRE-CONFIGURED TRANSLATION RULES
2607
CONFIGURE TRANSLATION RULES
2608
GENERATE OUTPUT MESSAGE BASED ON TRANSLATION RULES

FIG. 26

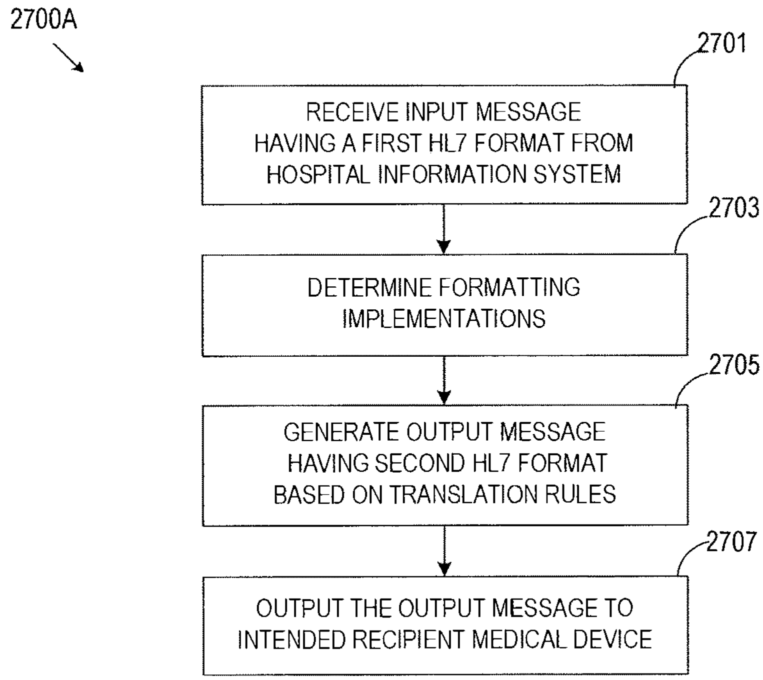


FIG. 27A

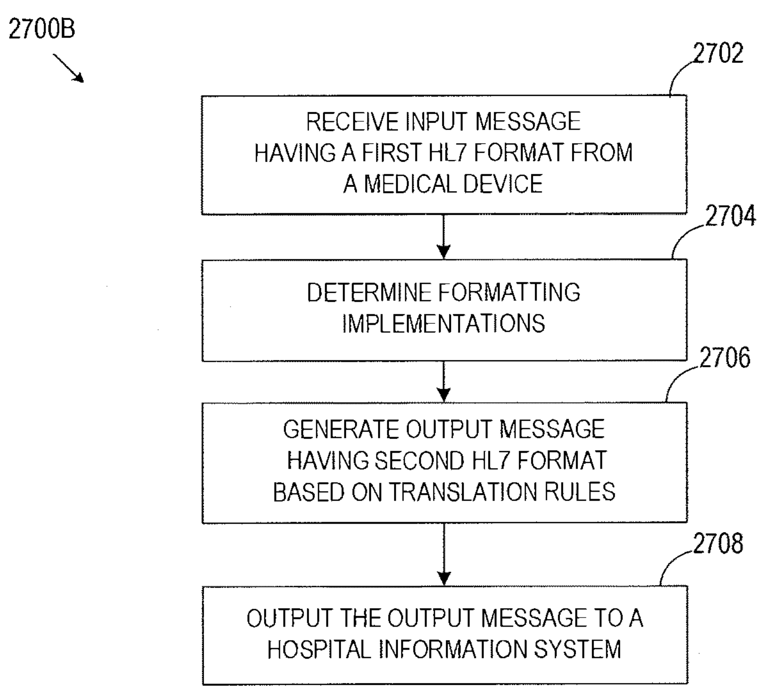


FIG. 27B

2800

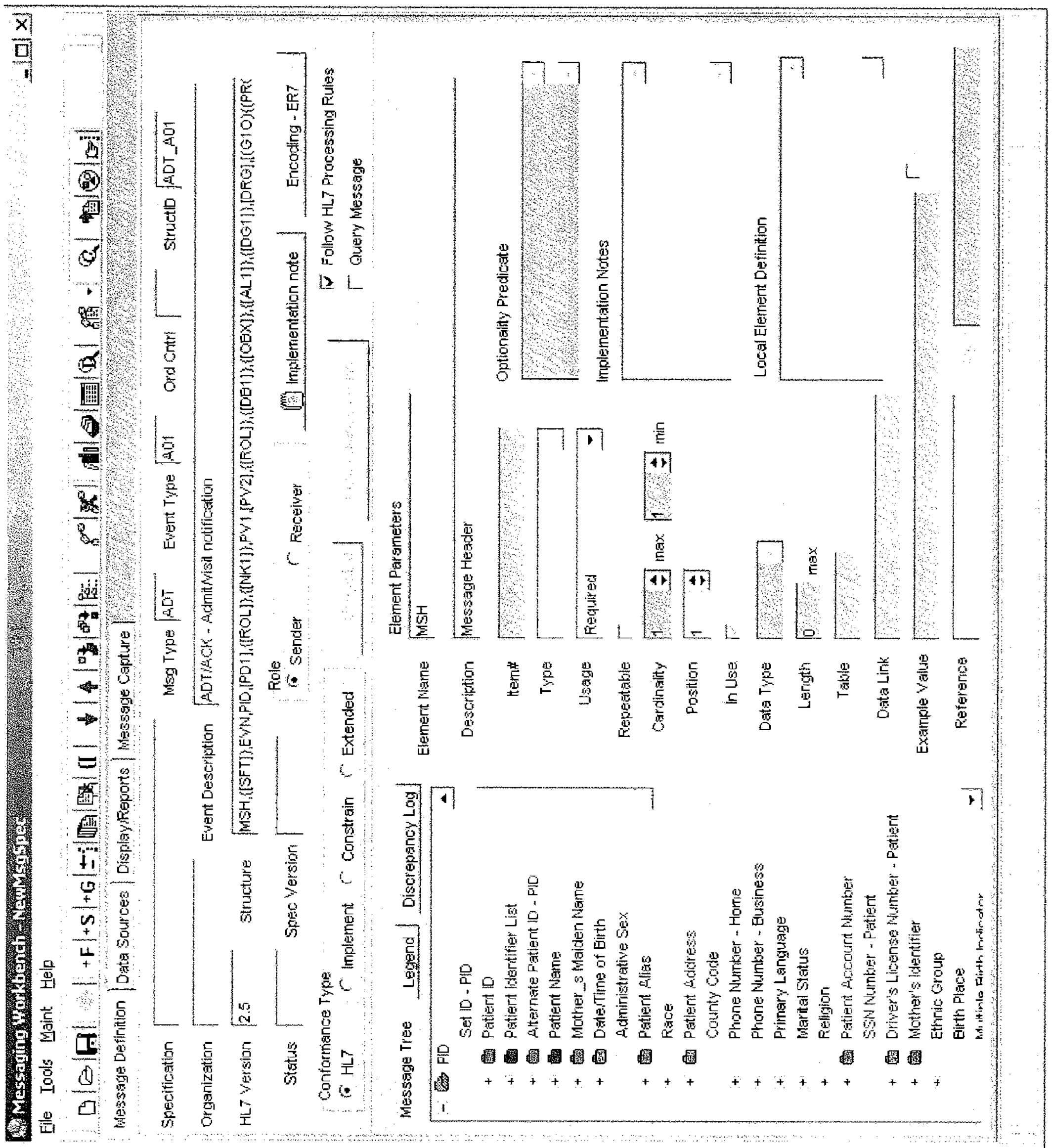

Messaging Workbench - NewMsgSpec
File Tools Maint Help
Message Definition
Data Sources
Display/Reports
Message Capture
Specification
Organization
HL7 Version 2.5
Status
Msg Type ADT
Event Type A01
Ord Cntrl
StructID ADT_A01
Event Description ADT/ACK - Admit/visit notification
Structure MSH,[{SFT}],EVN,PID,[PD1],[{ROL}],[{NK1}],PV1,[PV2],[{ROL}],[{DB1}],[{OBX}],[{AL1}],[{DG1}],[DRG],[{G1O}{[PR(
Spec Version
Role
Sender
Receiver
Implementation note
Encoding - ER7
Conformance Type
HL7
Implement
Constrain
Extended
Follow HL7 Processing Rules
Query Message
Message Tree
Legend
Discrepancy Log
PID
Set ID - PID
Patient ID
Patient Identifier List
Alternate Patient ID - PID
Patient Name
Mother_s Maiden Name
Date/Time of Birth
Administrative Sex
Patient Alias
Race
Patient Address
County Code
Phone Number - Home
Phone Number - Business
Primary Language
Marital Status
Religion
Patient Account Number
SSN Number - Patient
Driver's License Number - Patient
Mother's Identifier
Ethnic Group
Birth Place
Element Parameters
Element Name MSH
Description Message Header
Item#
Type
Usage Required
Repeatable
Cardinality 1 max 1 min
Position 1
In Use
Data Type
Length 0 max
Table
Data Link
Example Value
Reference
Optionality Predicate
Implementation Notes
Local Element Definition

FIG. 28

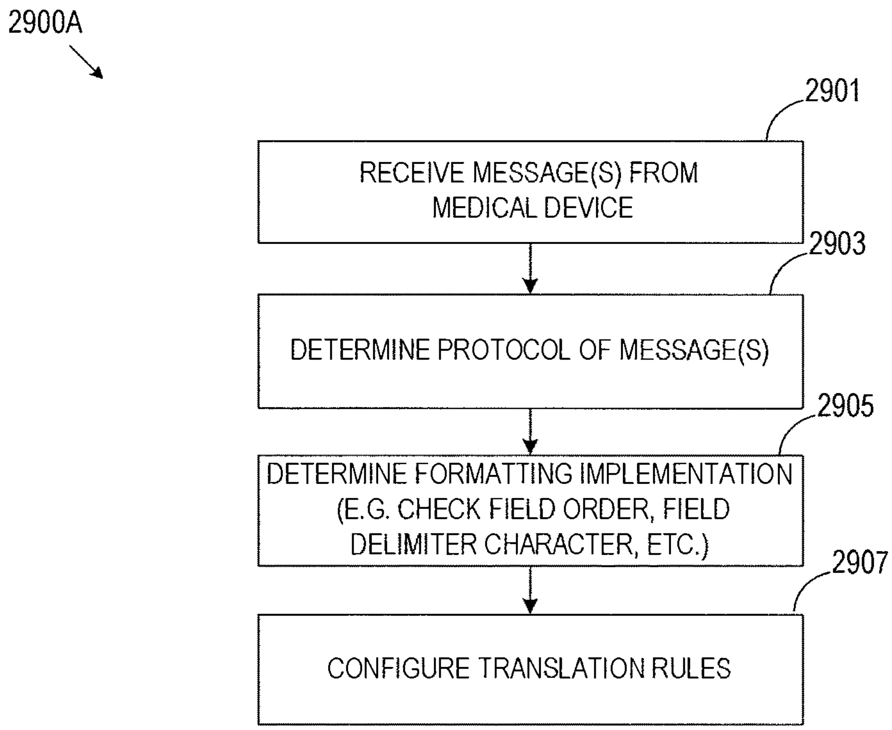


FIG. 29A

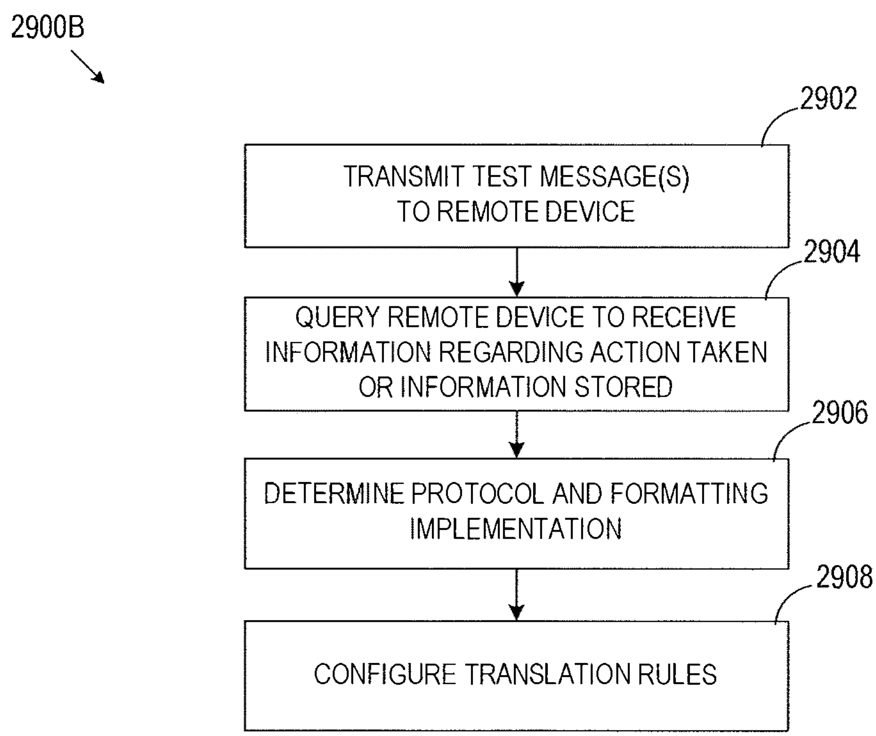


FIG. 29B

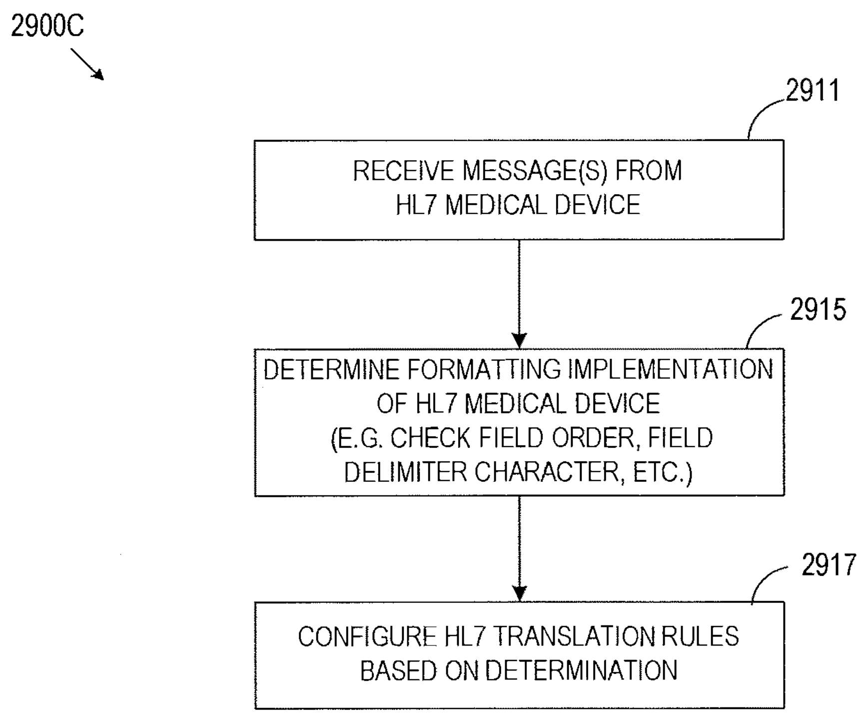


FIG. 29C

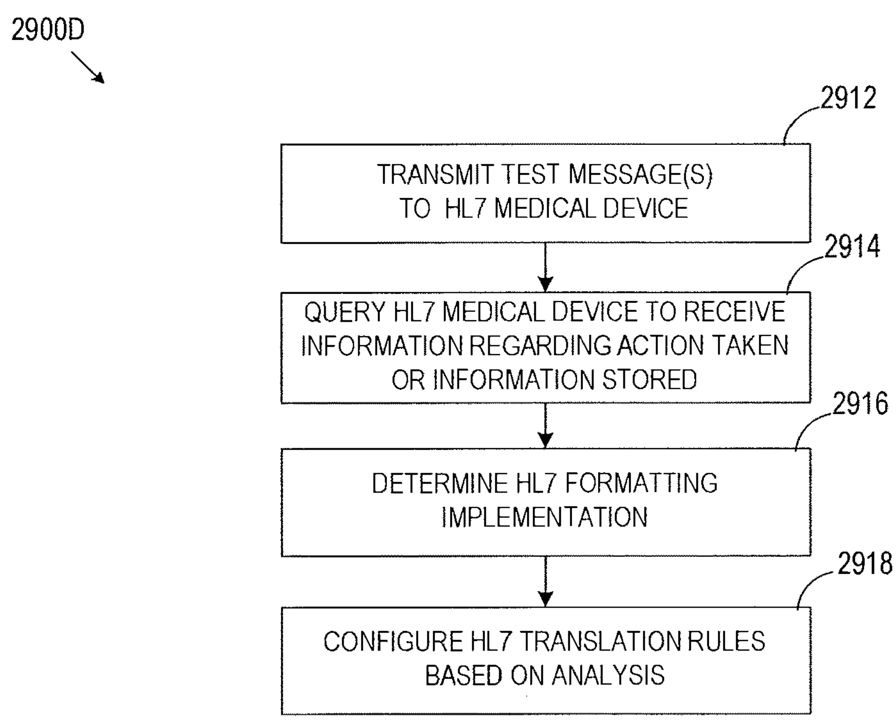


FIG. 29D

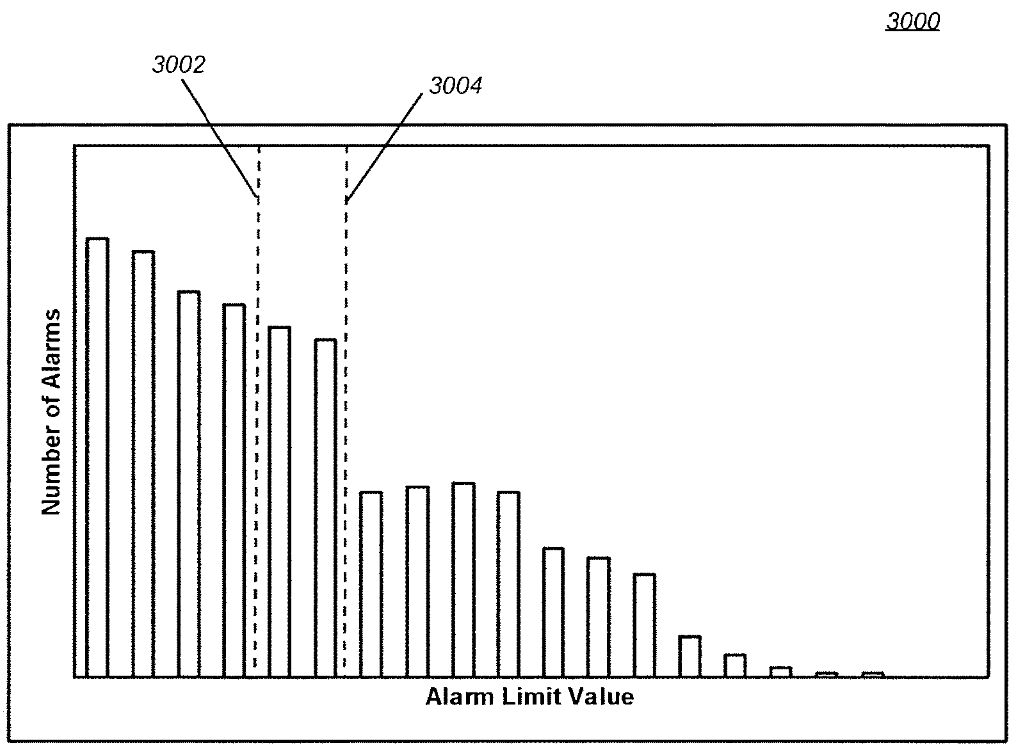


FIG 30

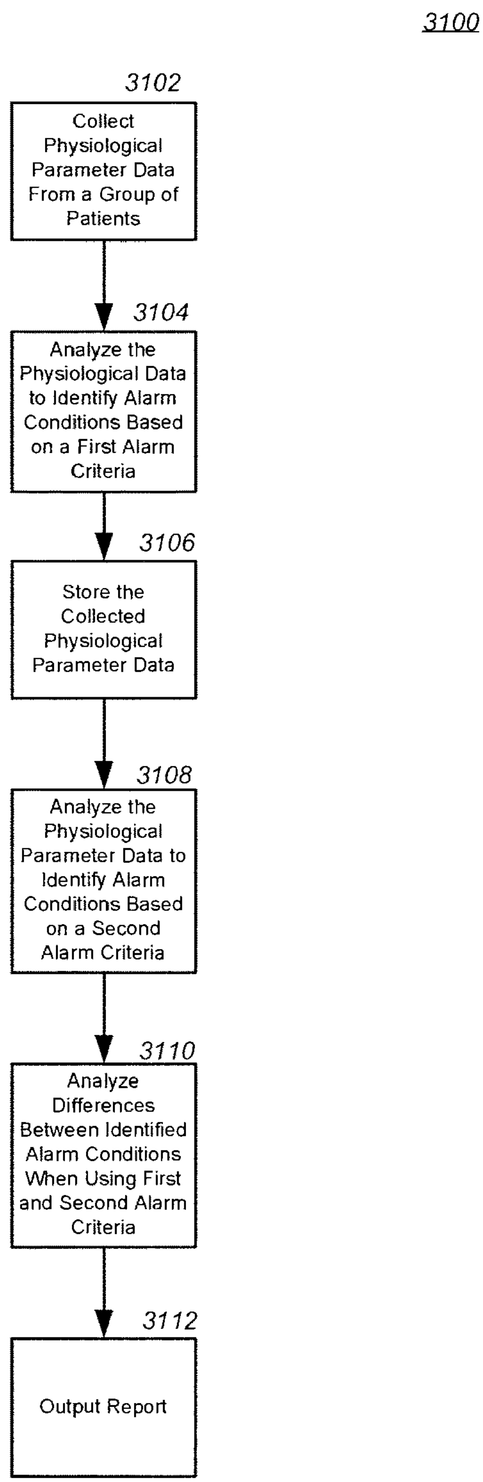

3100
3102
Collect Physiological Parameter Data From a Group of Patients
3104
Analyze the Physiological Data to Identify Alarm Conditions Based on a First Alarm Criteria
3106
Store the Collected Physiological Parameter Data
3108
Analyze the Physiological Parameter Data to Identify Alarm Conditions Based on a Second Alarm Criteria
3110
Analyze Differences Between Identified Alarm Conditions When Using First and Second Alarm Criteria
3112
Output Report

FIG 31

3200

	Number of Alarms	Change Versus Actual Alarm Criteria
Simulated Alarm Criteria #1	--	--
Simulated Alarm Criteria #2	--	--
Simulated Alarm Criteria #3	--	--
Simulated Alarm Criteria #4	--	--
Simulated Alarm Criteria #5	--	--

FIG 32

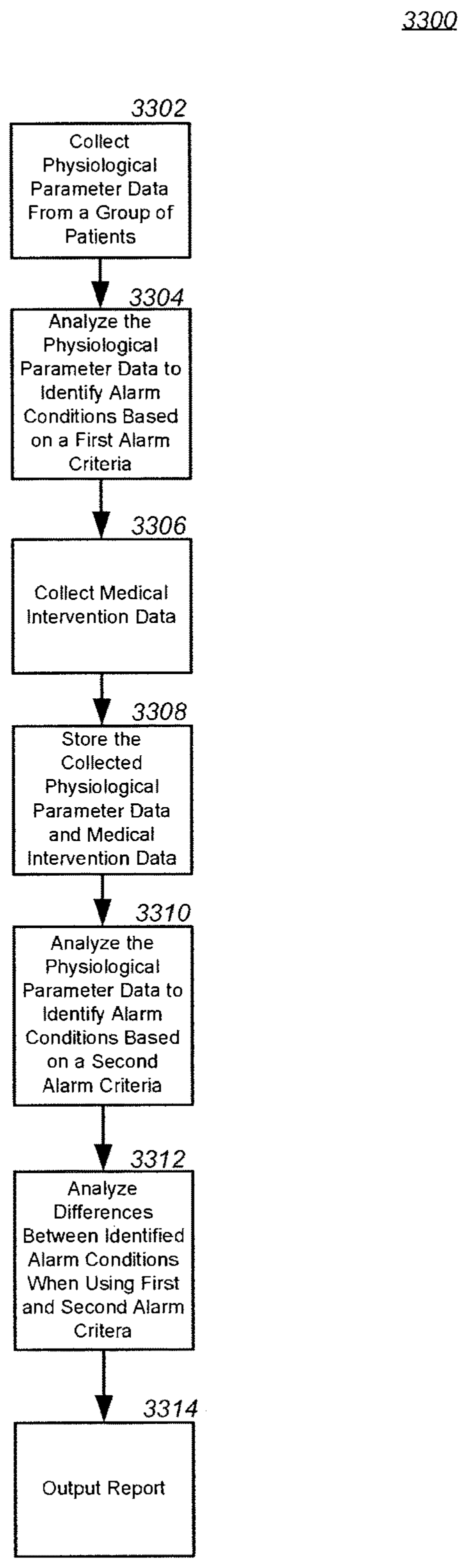

3300
3302
Collect Physiological Parameter Data From a Group of Patients
3304
Analyze the Physiological Parameter Data to Identify Alarm Conditions Based on a First Alarm Criteria
3306
Collect Medical Intervention Data
3308
Store the Collected Physiological Parameter Data and Medical Intervention Data
3310
Analyze the Physiological Parameter Data to Identify Alarm Conditions Based on a Second Alarm Criteria
3312
Analyze Differences Between Identified Alarm Conditions When Using First and Second Alarm Critera
3314
Output Report

FIG 33

3400

	Number of Alarms	Change Versus Actual Alarm Setting	Estimated False Negatives Detected	Estimated Accurate Alarms Undetected
Simulated Alarm Criteria #1	--	--	--	--
Simulated Alarm Criteria #2	--	--	--	--
Simulated Alarm Criteria #3	--	--	--	--
Simulated Alarm Criteria #4	--	--	--	--
Simulated Alarm Criteria #5	--	--	--	--

FIG 34

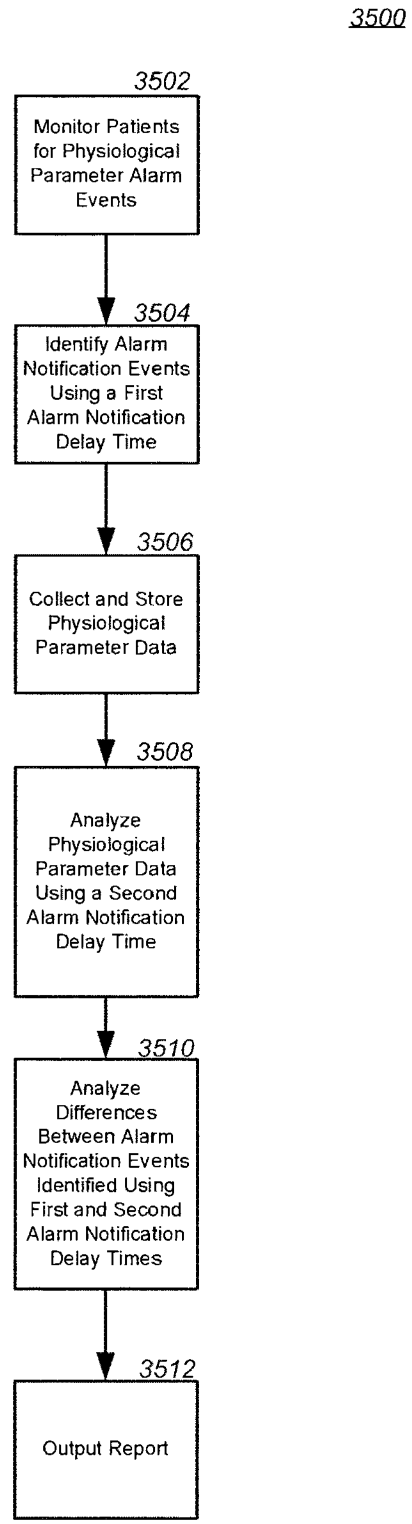

3500
3502
Monitor Patients for Physiological Parameter Alarm Events
3504
Identify Alarm Notification Events Using a First Alarm Notification Delay Time
3506
Collect and Store Physiological Parameter Data
3508
Analyze Physiological Parameter Data Using a Second Alarm Notification Delay Time
3510
Analyze Differences Between Alarm Notification Events Identified Using First and Second Alarm Notification Delay Times
3512
Output Report

FIG 35

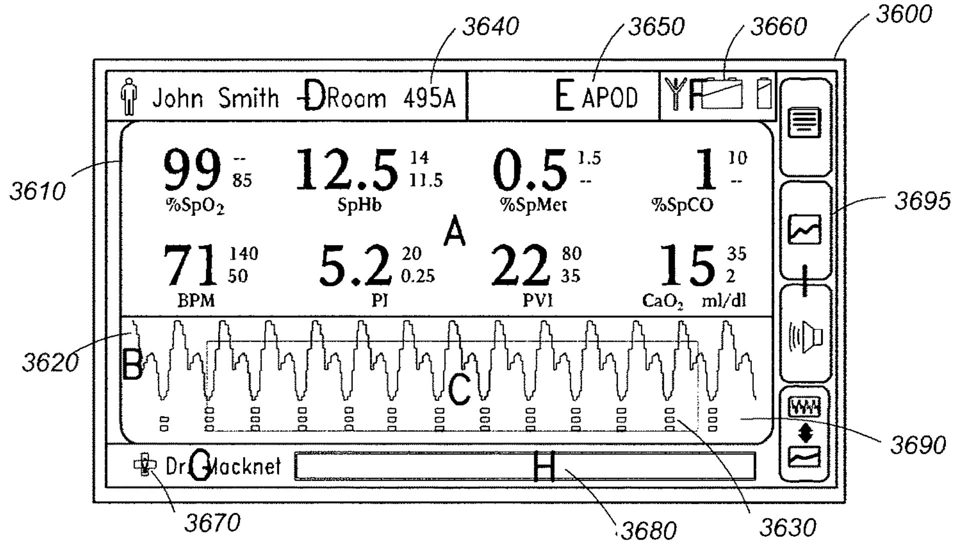


FIG 36A

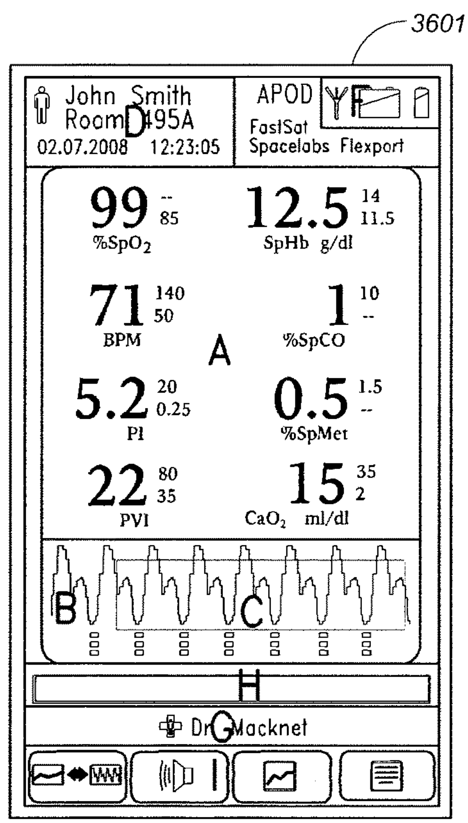


FIG 36B

8 PARAMETERS

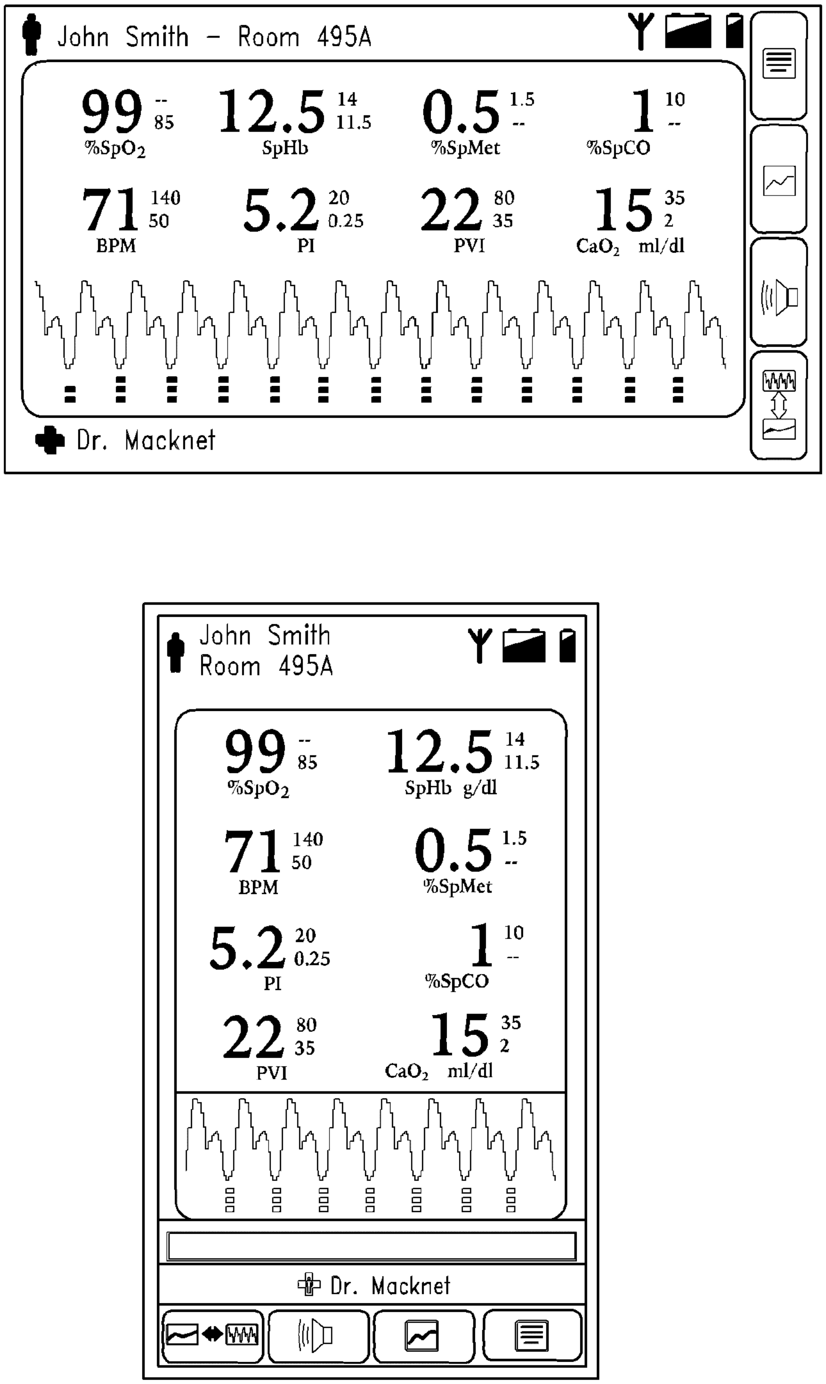
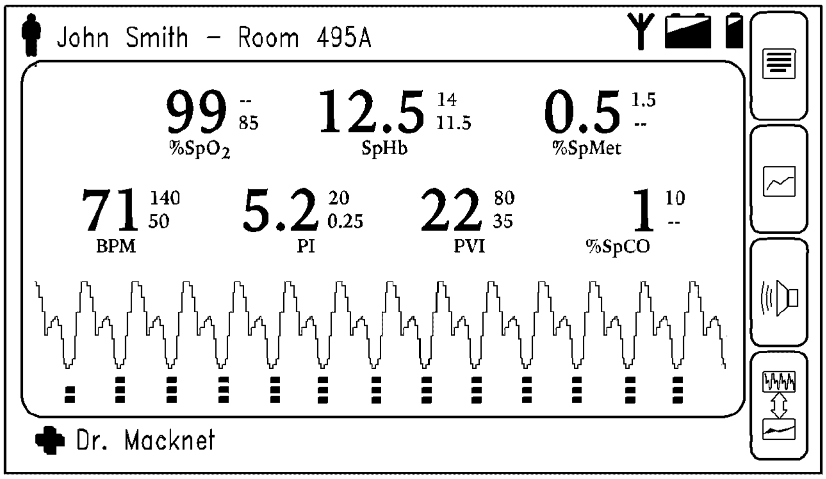


FIG. 37A

7 PARAMETERS



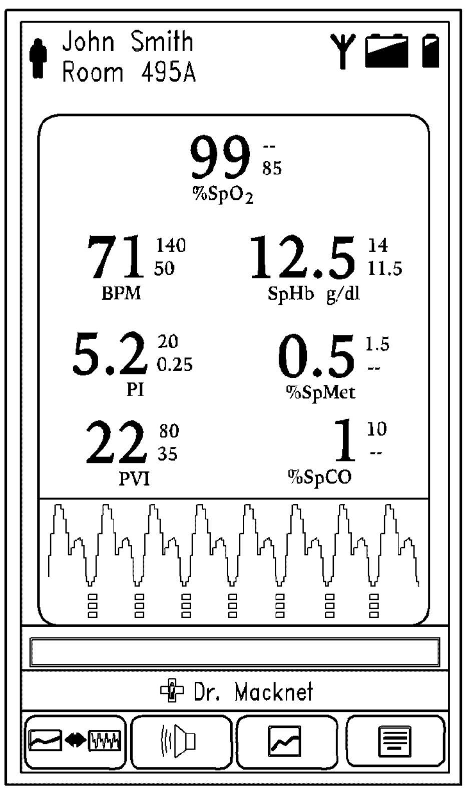
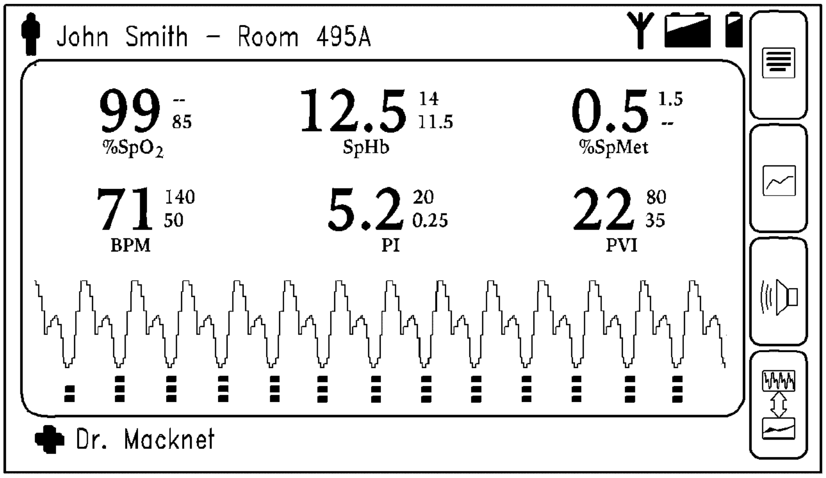


FIG. 37B

6 PARAMETERS



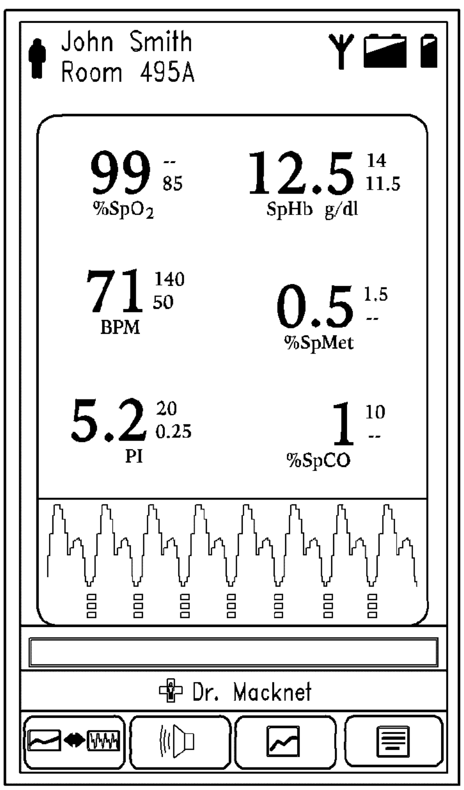
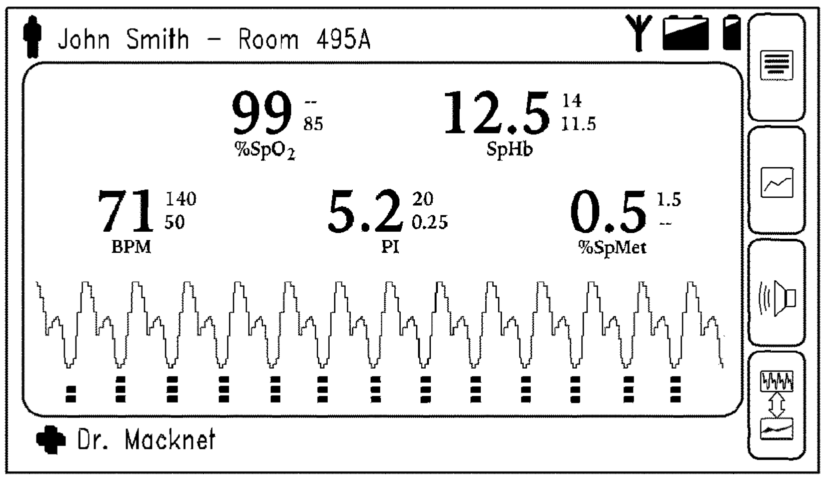


FIG. 37C

5 PARAMETERS



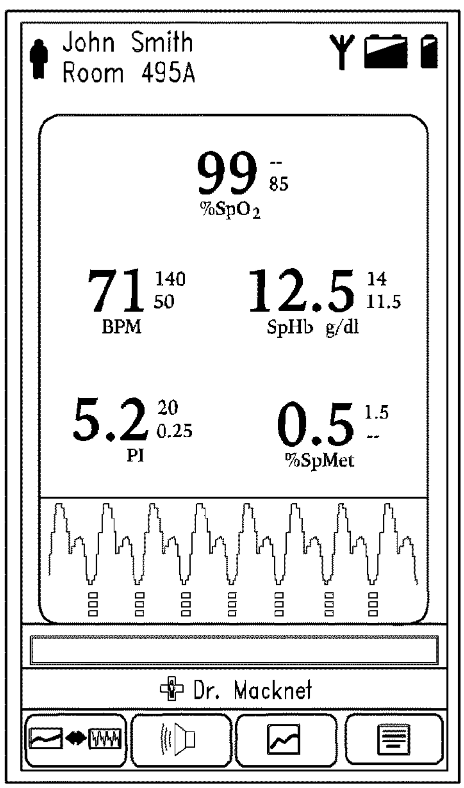
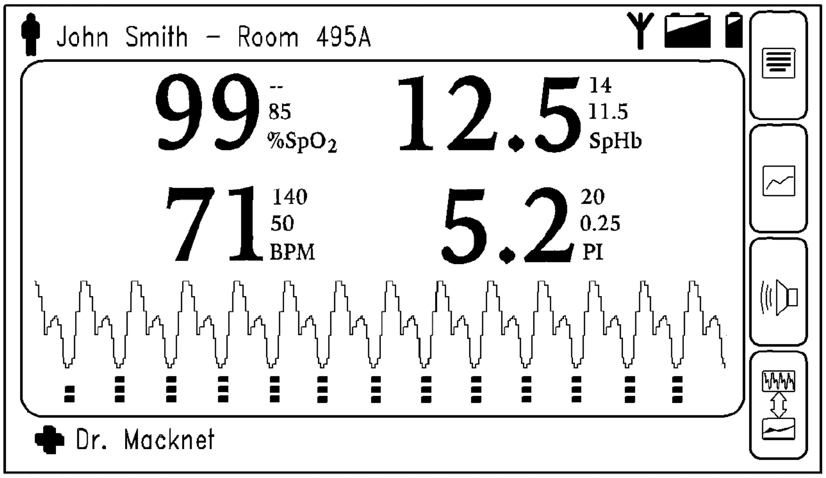


FIG. 37D

4 PARAMETERS



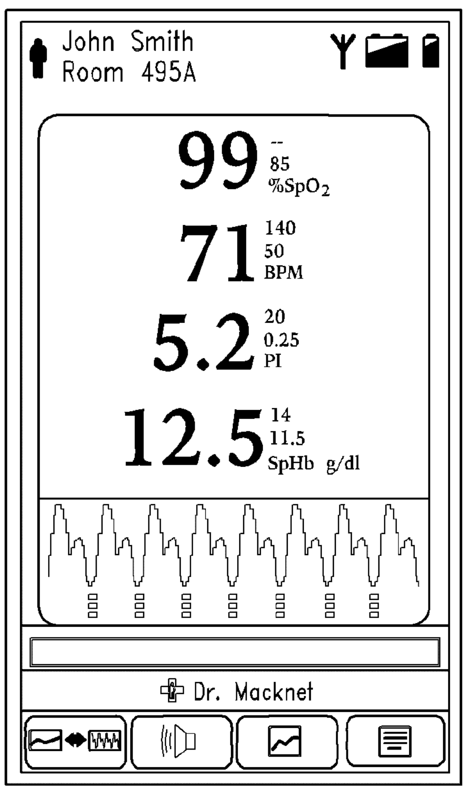


FIG. 37E

3 PARAMETERS

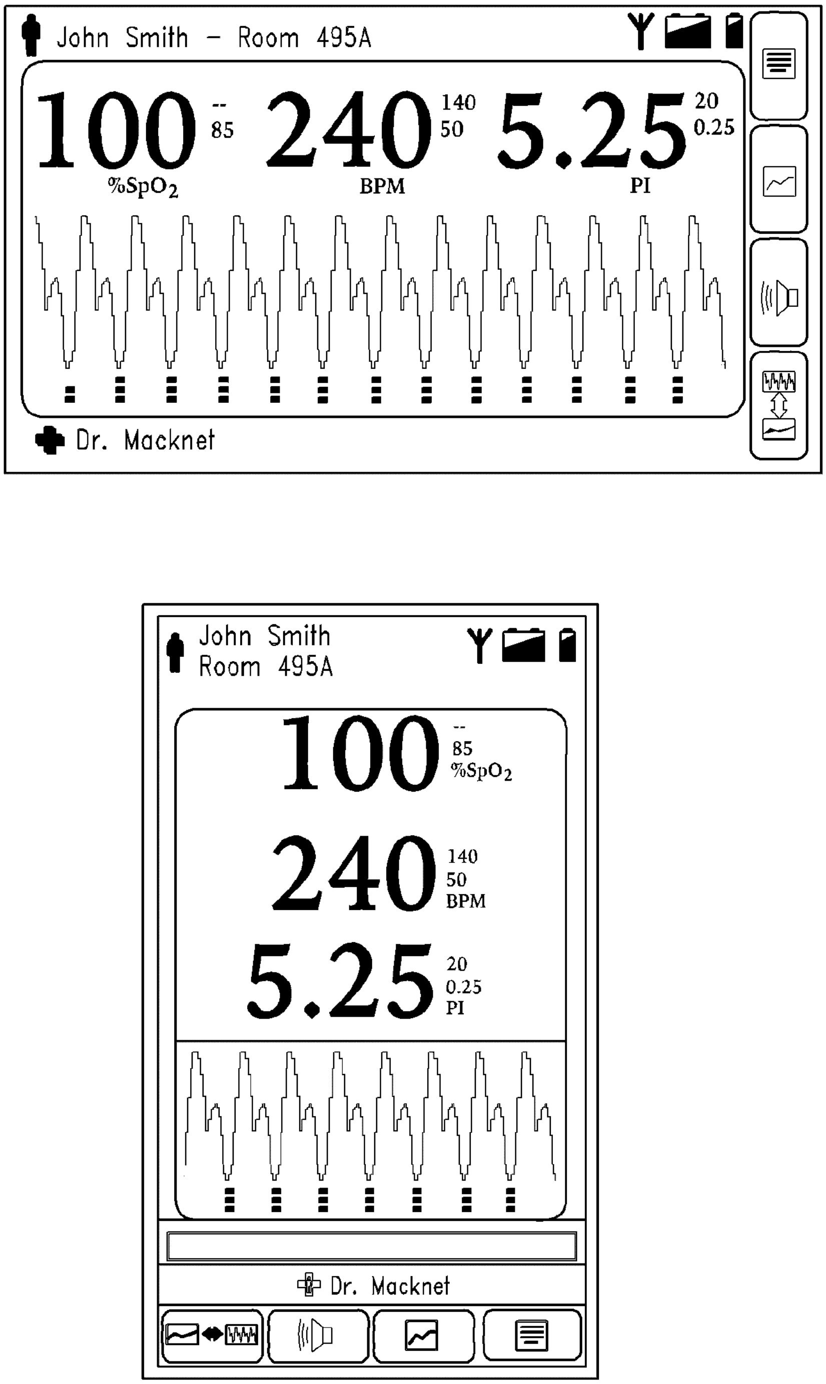


FIG. 37F

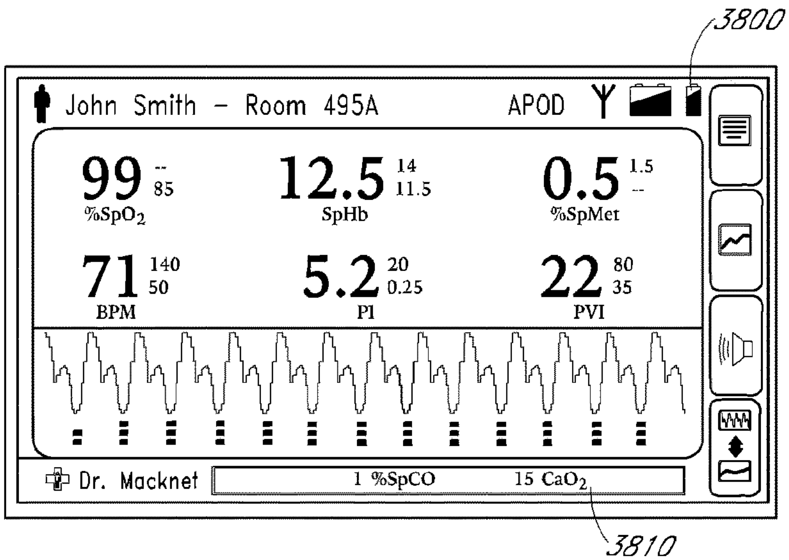


FIG. 38A

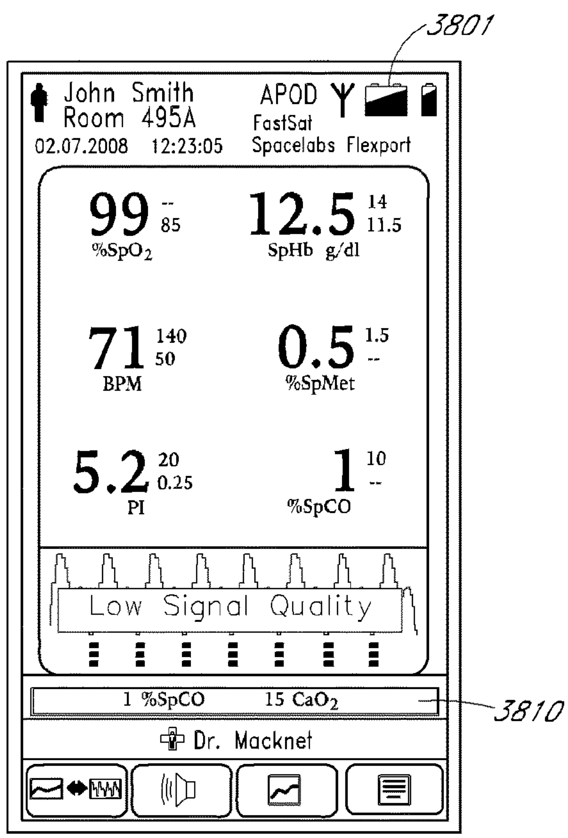


FIG. 38B

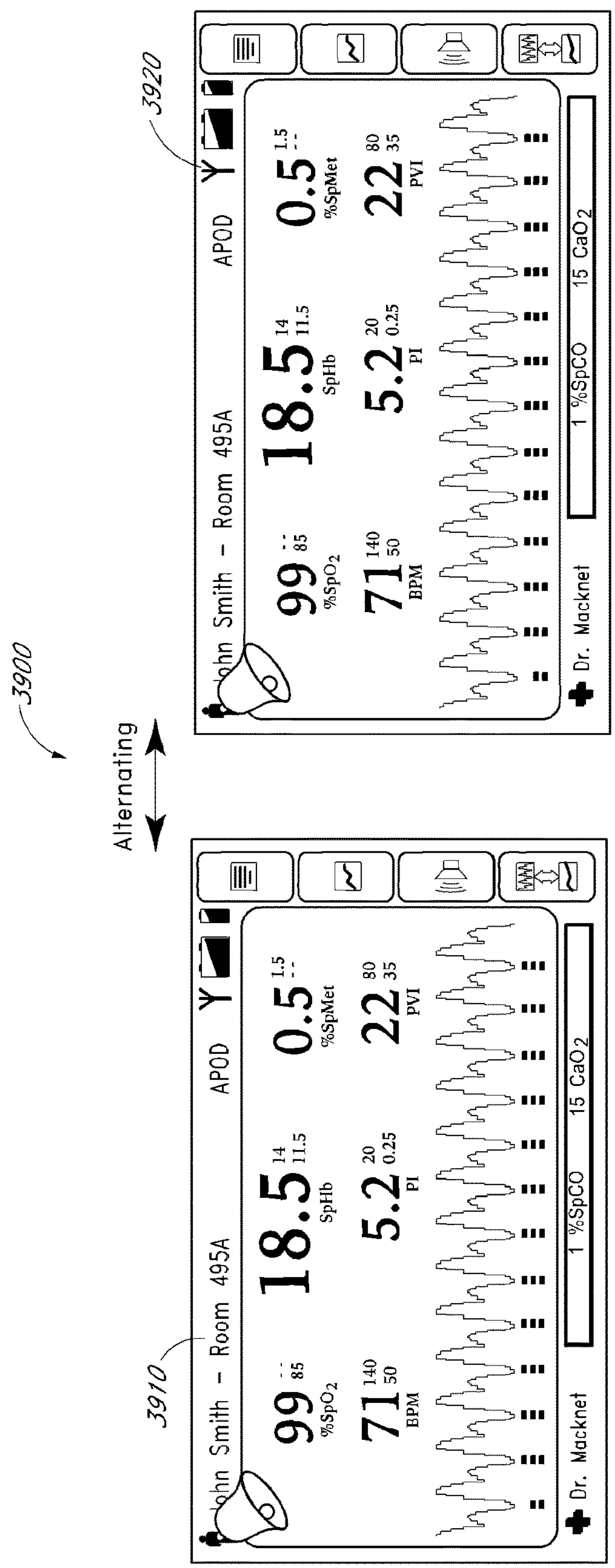

3900
3910
3920
Alternating
John Smith - Room 495A
APOD
99
%SpO2
85
71
BPM
140
50
18.5
SpHb
14
11.5
5.2
PI
20
0.25
0.5
%SpMet
1.5
22
PVI
80
35
1 %SpCO
15 CaO2
Dr. Macknet

FIG. 39A

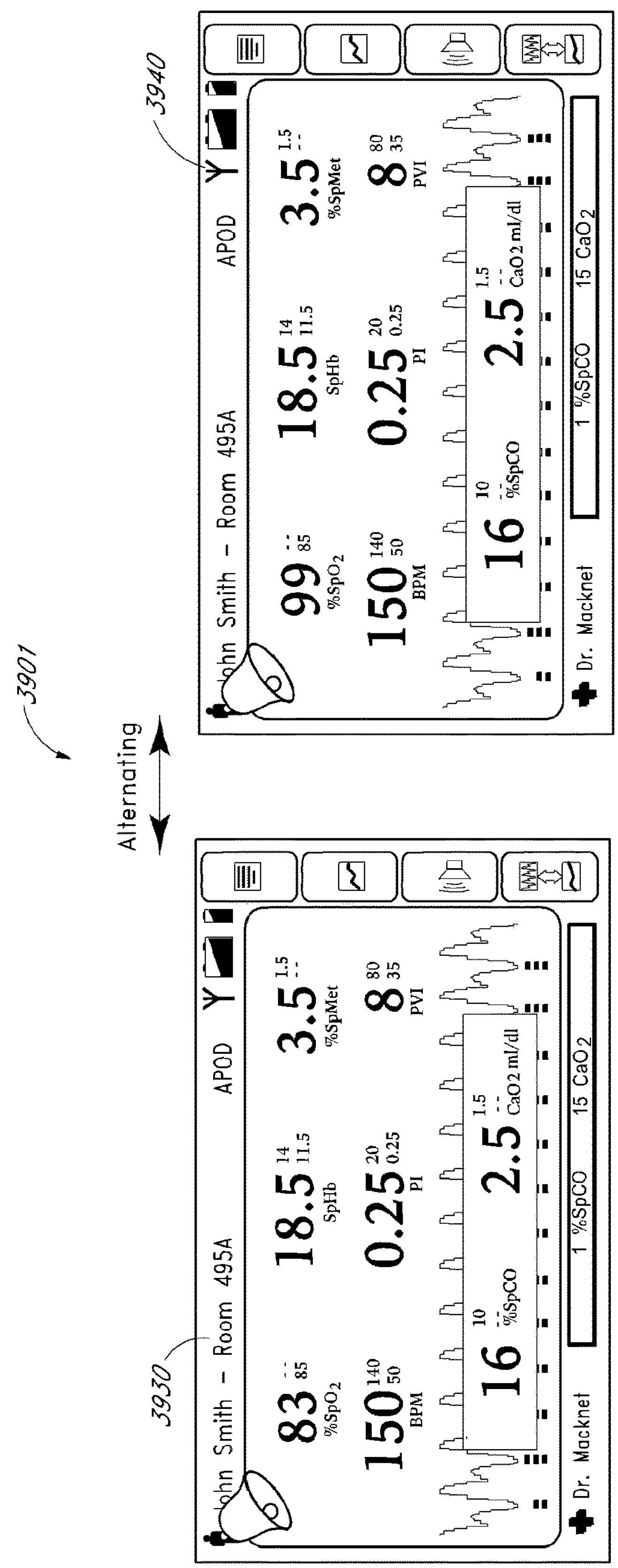

3940
3901
3930
Alternating
John Smith - Room 495A
APOD
99
%SpO2
83
150
BPM
18.5
SpHb
0.25
PI
3.5
%SpMet
8
PVI
16
%SpCO
2.5
CaO2 ml/dl
1 %SpCO
15 CaO2
Dr. Macknet

FIG. 39B

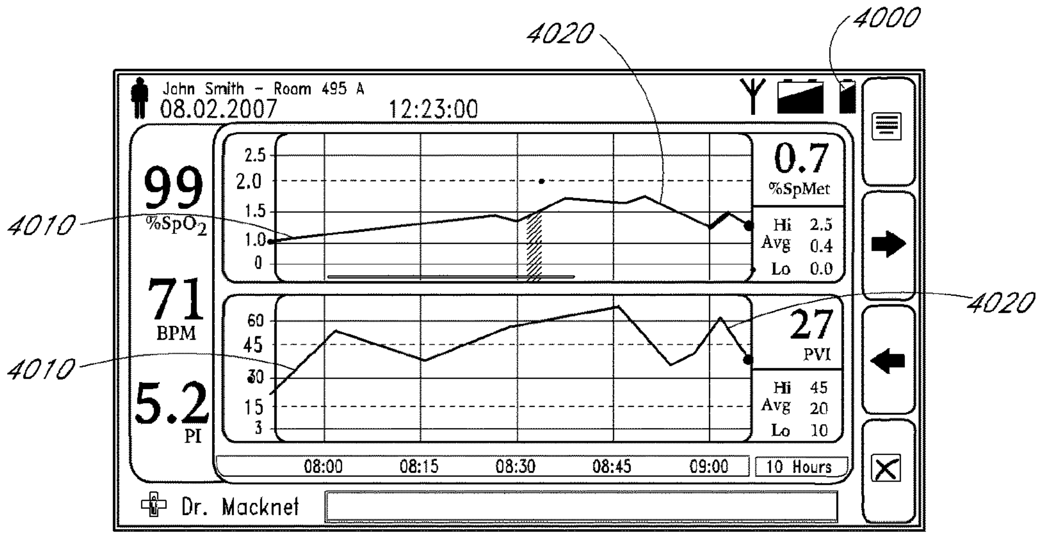


FIG. 40A

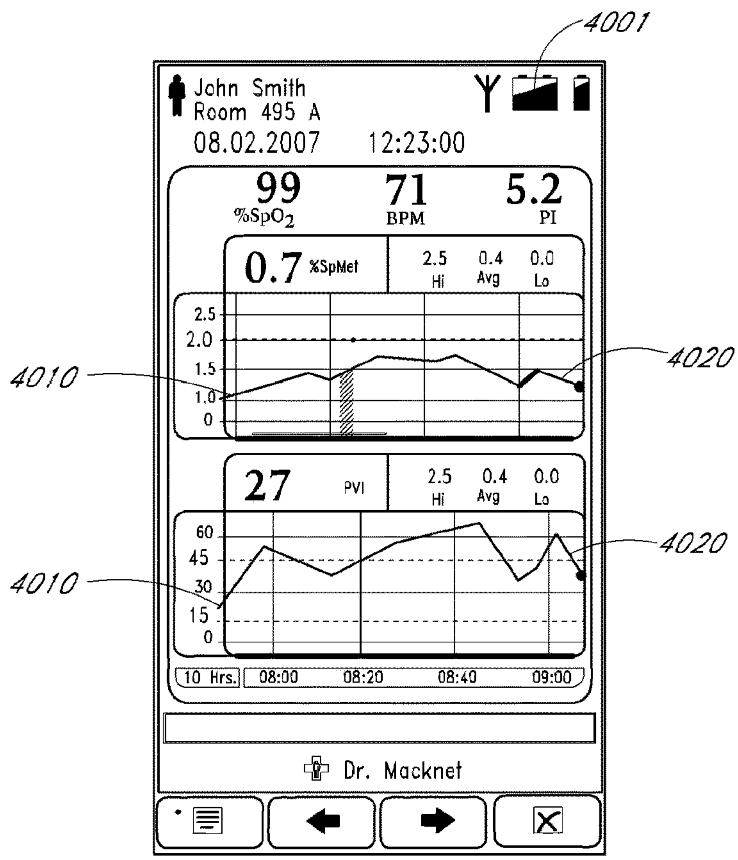


FIG. 40B

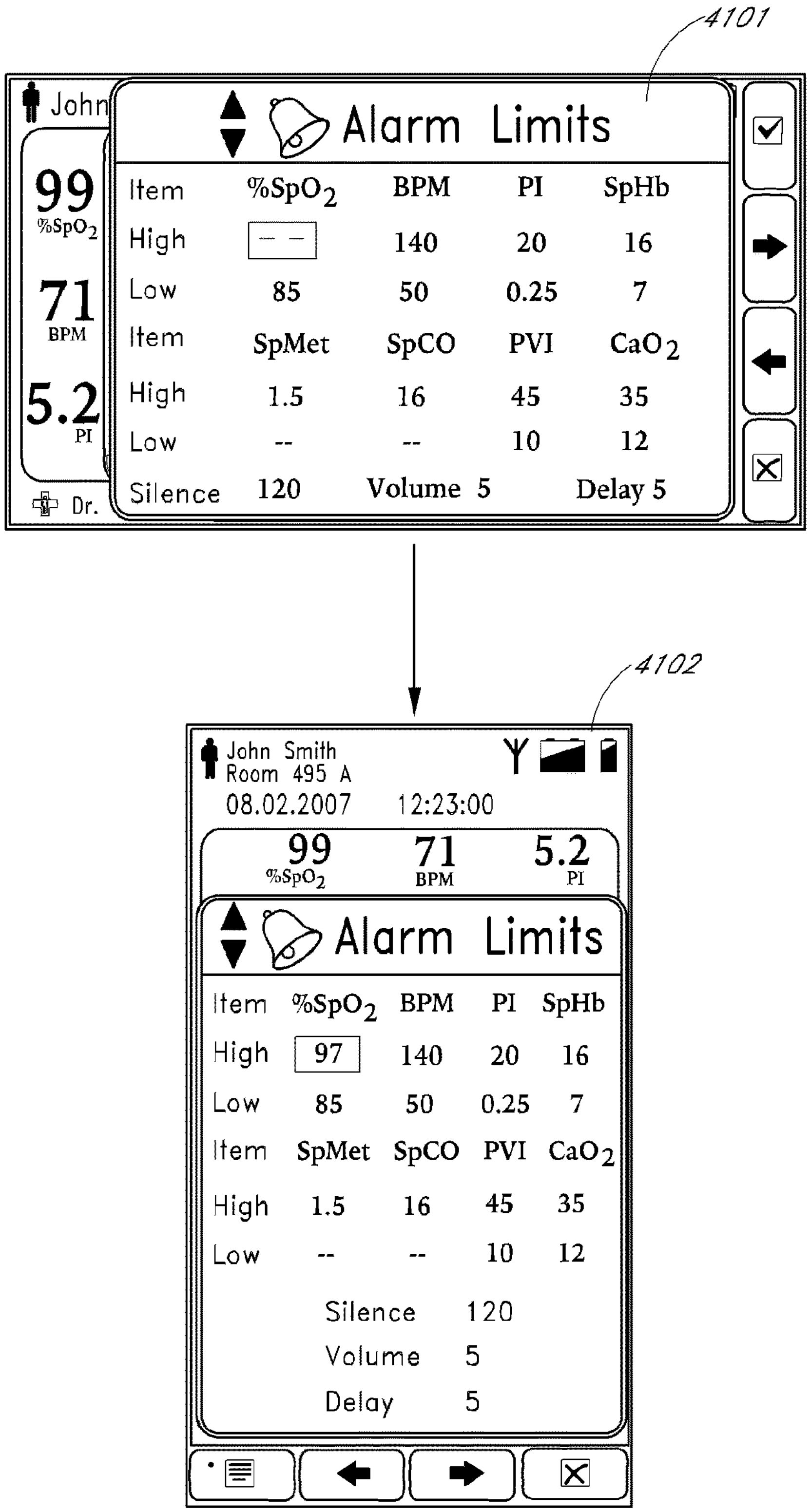

4101
John
99
%SpO2
71
BPM
5.2
PI
Dr.
Alarm Limits
Item %SpO2 BPM PI SpHb
High -- 140 20 16
Low 85 50 0.25 7
Item SpMet SpCO PVI CaO2
High 1.5 16 45 35
Low -- -- 10 12
Silence 120 Volume 5 Delay 5
4102
John Smith
Room 495 A
08.02.2007 12:23:00
99
%SpO2
71
BPM
5.2
PI
Alarm Limits
Item %SpO2 BPM PI SpHb
High 97 140 20 16
Low 85 50 0.25 7
Item SpMet SpCO PVI CaO2
High 1.5 16 45 35
Low -- -- 10 12
Silence 120
Volume 5
Delay 5

FIG. 41

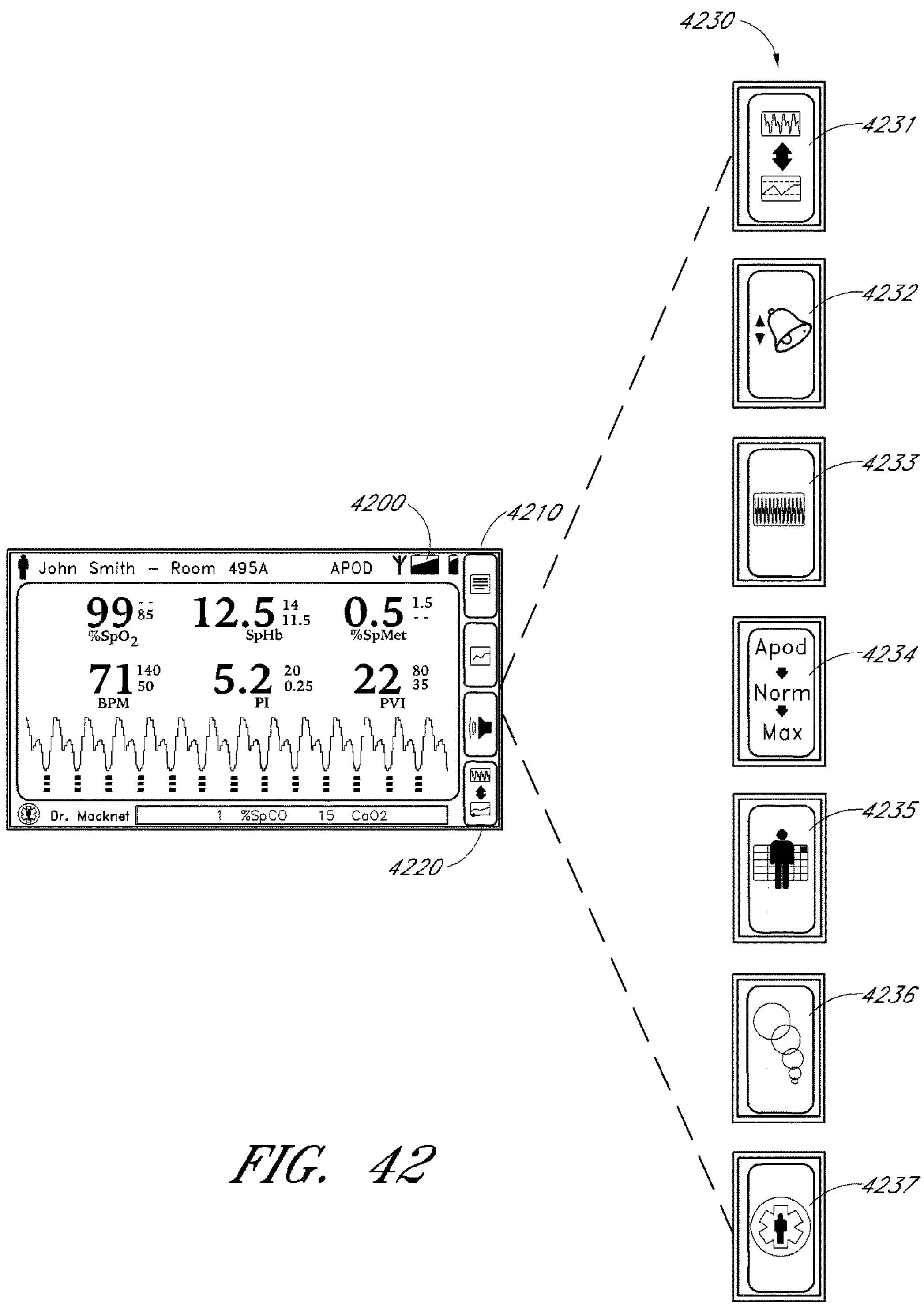
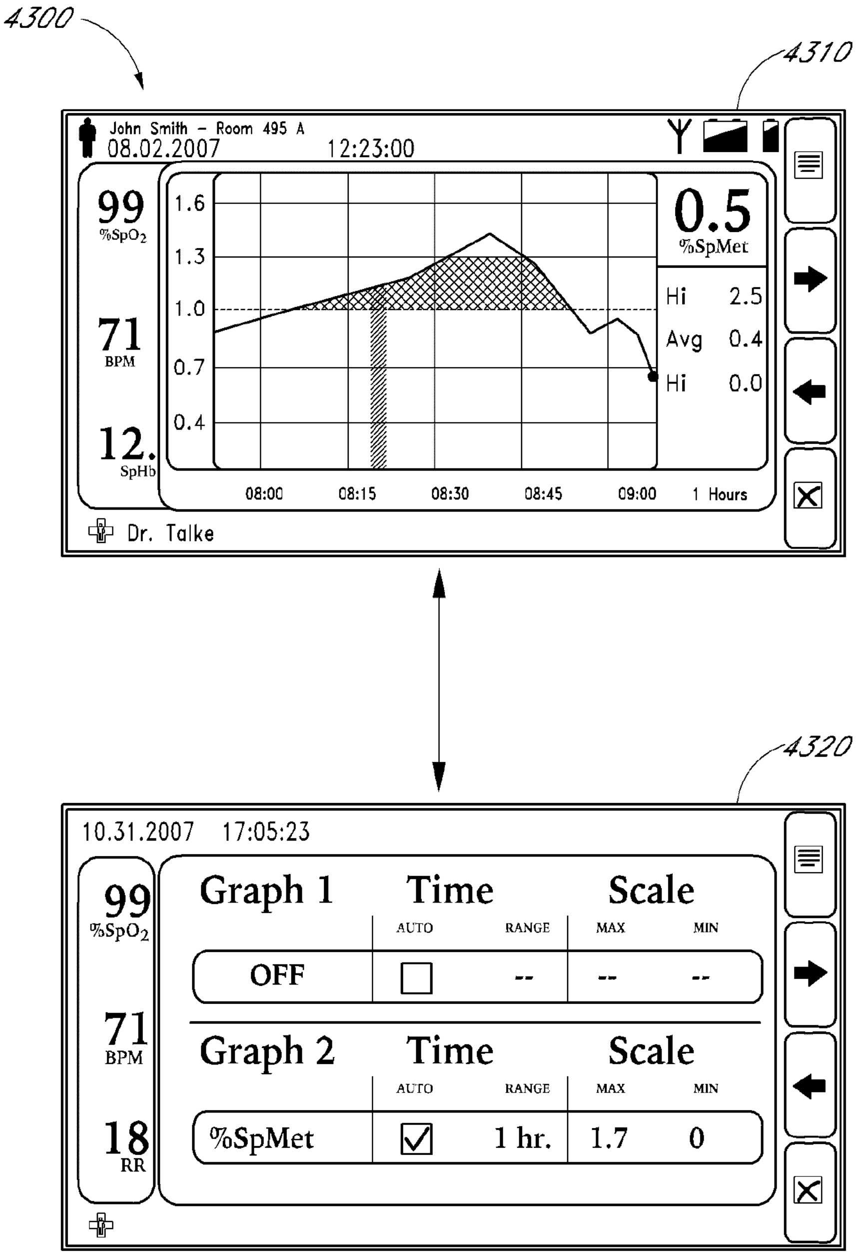
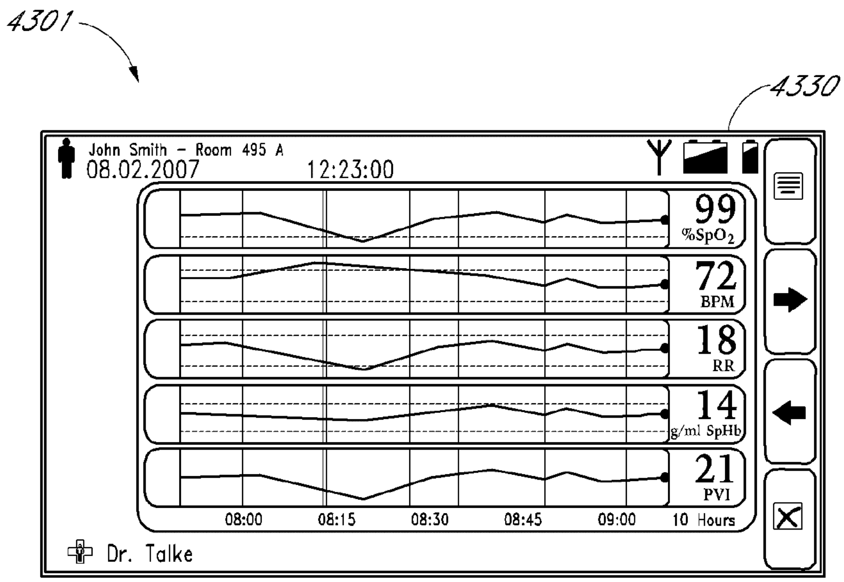

4230
4231
4232
4233
4234
Apod
Norm
Max
4235
4236
4237
4200
4210
John Smith – Room 495A
APOD
99
85
%SpO2
12.5
14
11.5
SpHb
0.5
1.5
%SpMet
71
140
50
BPM
5.2
20
0.25
PI
22
80
35
PVI
Dr. Macknet
1 %SpCO 15 CaO2
4220

FIG. 42



4300
4310
John Smith – Room 495 A
08.02.2007
12:23:00
99
%SpO2
71
BPM
12.
SpHb
1.6
1.3
1.0
0.7
0.4
0.5
%SpMet
Hi 2.5
Avg 0.4
Hi 0.0
08:00
08:15
08:30
08:45
09:00
1 Hours
Dr. Talke
4320
10.31.2007 17:05:23
99
%SpO2
71
BPM
18
RR
Graph 1
Time
Scale
AUTO
RANGE
MAX
MIN
OFF
--
--
--
Graph 2
Time
Scale
AUTO
RANGE
MAX
MIN
%SpMet
1 hr.
1.7
0

FIG. 43A


4301
4330
John Smith – Room 495 A
08.02.2007
12:23:00
99
%SpO2
72
BPM
18
RR
14
g/ml SpHb
21
PVI
08:00
08:15
08:30
08:45
09:00
10 Hours
Dr. Talke

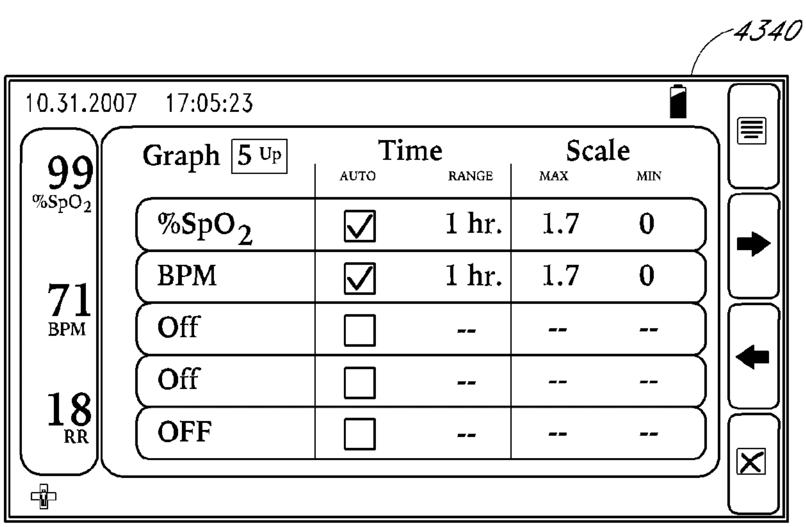

4340
10.31.2007 17:05:23
99
%SpO2
71
BPM
18
RR
Graph 5 Up
Time
AUTO
RANGE
Scale
MAX
MIN
%SpO2 1 hr. 1.7 0
BPM 1 hr. 1.7 0
Off -- -- --
Off -- -- --
OFF -- -- --

FIG. 43B

PHYSIOLOGICAL PARAMETER ALARM DELAY

CROSS-REFERENCE TO RELATED APPLICATIONS

This application is a continuation of U.S. patent application Ser. No. 14/975,564, filed Dec. 18, 2015, entitled "MEDICAL COMMUNICATION PROTOCOL TRANSLATOR," which is a divisional of U.S. patent application Ser. No. 12/717,081, now U.S. Pat. No. 9,218,454, filed Mar. 3, 2010, and entitled "MEDICAL MONITORING SYSTEM," which claims a priority benefit to U.S. Provisional Application No. 61/209,147, filed Mar. 4, 2009, and entitled "PROXIMITY DISPLAY MONITOR," and to U.S. Provisional Application No. 61/296,439, filed Jan. 19, 2010, and entitled "MEDICAL MONITORING SYSTEM," the entire contents of each of which are hereby incorporated by reference herein.

BACKGROUND

Field of the Invention

This disclosure relates to systems, devices, and methods with applications in, for example, hospitals and other patient care facilities. For example, the systems, devices, and methods described herein can be used for acquiring physiological information from patients, analyzing the physiological information, and communicating the physiological information to clinicians and other systems or devices.

Description of the Related Art

Hospitals, nursing homes, and other patient care facilities typically include patient monitoring devices at one or more bedsides in the facility. Patient monitoring devices generally include sensors, processing equipment, and displays for obtaining and analyzing a medical patient's physiological parameters. Physiological parameters include, for example, respiratory rate, SpO_2 level, pulse, and blood pressure, among others. Clinicians, including doctors, nurses, and certain other medical personnel use the physiological parameters obtained from the medical patient to diagnose illnesses and to prescribe treatments. Clinicians also use the physiological parameters to monitor a patient during various clinical situations to determine whether to increase the level of medical care given to the patient.

Patient monitors capable of measuring pulse oximetry parameters, such as SpO2 and pulse rate in addition to advanced parameters, such as HbCO, HbMet and total hemoglobin (Hbt) and corresponding multiple wavelength optical sensors are described in at least U.S. patent application Ser. No. 11/367,013, filed Mar. 1, 2006 and entitled Multiple Wavelength Sensor Emitters and U.S. patent application Ser. No. 11/366,208, filed Mar. 1, 2006 and entitled Noninvasive Multi-Parameter Patient Monitor, both assigned to Masimo Laboratories, Irvine, Calif. (Masimo Labs) and both incorporated by reference herein. Further, noninvasive blood parameter monitors and corresponding multiple wavelength optical sensors, such as Rainbow™ adhesive and reusable sensors and RAD-57™ and Radical-7™ monitors for measuring SpO2, pulse rate, perfusion index, signal quality, HbCO and HbMet among other parameters are also available from Masimo Corporation, Irvine, Calif. (Masimo).

Advanced physiological monitoring systems may incorporate pulse oximetry in addition to advanced features for the calculation and display of other blood parameters, such as carboxyhemoglobin (HbCO), methemoglobin (HbMet)

and total hemoglobin (Hbt), as a few examples. Advanced physiological monitors and corresponding multiple wavelength optical sensors capable of measuring parameters in addition to SpO2, such as HbCO, HbMet and Hbt are described in at least U.S. patent application Ser. No. 11/367,013, filed Mar. 1, 2006, titled Multiple Wavelength Sensor Emitters and U.S. patent application Ser. No. 11/366,208, filed Mar. 1, 2006, titled Noninvasive Multi-Parameter Patient Monitor, assigned to Masimo Labs and incorporated by reference herein. Further, noninvasive blood parameter monitors and corresponding multiple wavelength optical sensors, such as Rainbow™ adhesive and reusable sensors and RAD-57™ and Radical-7™ monitors for measuring SpO2, pulse rate, perfusion index (PI), signal quality (SiQ), pulse variability index (PVI), HbCO and HbMet among other parameters are also available from Masimo.

SUMMARY OF THE INVENTION

Various medical monitoring devices, systems, and methods are described herein. In some embodiments, a medical monitoring device or system is capable of detecting the presence of a clinician and, for example, taking some action in response to detection of the clinician's presence. In some embodiments, a medical monitoring system is capable of detecting the location of a number of medical devices, clinicians, and/or patients in a hospital or other patient care facility. The detected locations can then be used to take some location-based action, such as, for example, changing the configuration of a medical device.

Various devices, systems and methods for facilitating communication between medical monitoring devices or systems using a medical communication protocol translator are described herein. A medical communication protocol translator can be configured to facilitate communication between medical devices that are programmed to communicate with different protocol formats. The medical communication protocol translator can receive an input message formatted according to a first protocol format from a first medical device and to output an output message formatted according to a second protocol format supported by a second medical device using a set of translation rules. For example, a medical communication protocol translator can receive an input message from a hospital information system formatted according to a first HL7 protocol format and output an output message formatted according to a second HL7 protocol format based on a comparison with the set of translation rules.

In some embodiments, a medical monitoring device or system is capable of collecting physiological parameter data from a number of patients, and using this data to simulate a variety of alarm condition detection criteria and/or alarm notification delay times. These simulated alarm condition detection criteria and/or alarm notification delay times can be analyzed and used to alter actual alarm condition detection criteria and/or alarm notification delay times that are used by, for example, bedside patient monitoring devices.

In certain embodiments, a medical patient monitoring device for monitoring physiological information includes an interface configured to receive physiological information from at least one patient. The device can further include a processor configured to perform a clinically-useful task based on the physiological information. The device can also include a detector for detecting the physical presence of a clinician token within a detection area in the vicinity of the medical patient monitoring device, where the clinician token is indicative of the identity of a clinician. Moreover, the

processor can be configured to take a first predetermined action in response to detection of the clinician token, where the first predetermined action is associated with the identity of the clinician.

In certain embodiments, a clinical system for determining the physical locations of a plurality of medical devices includes multiple medical patient monitoring devices that are capable of collecting physiological information from multiple patients. The clinical system can further include a distributed network of detectors that are capable of detecting wireless signals from the medical patient monitoring devices. The clinical system can also include a location monitoring server communicatively coupled to the detectors that is capable of determining estimates of the physical locations of the medical patient monitoring devices based upon the wireless signals detected from the detectors.

In various embodiments, a method for facilitating communication between first and second medical devices within a medical information network includes receiving a first input message from a first medical device, where the first input is generated according to a first communication protocol. The input message can identify a second medical device as an intended recipient of the input message. The method can further include translating the input message into an output message by applying one or more translation rules. The method can also include providing the output message to the second medical device, which is configured to receive and process the output message.

In certain embodiments, a medical device message translator configured to facilitate communication between first and second medical devices within a medical information network includes a communication interface module configured to receive a first input message from a first medical device, the first medical device having generated the input message according to a first communication protocol. The input message can identify a second medical device as an intended recipient of the input message. The translator can further include a rules module configured to store one or more predetermined translation rules and a translation module configured to translate the input message into an output message by applying one or more translation rules retrieved from the rules module. The second medical device can be configured to receive and process the output message.

In various embodiments, a method for converting messages communicated between medical devices and a hospital or clinical information system includes receiving an input message from a hospital information system that includes electronic patient medical records, where the content of the input message is formatted according to a first set of formatting rules allowed under a medical electronic communication protocol. The method can further include comparing the input message to a set of transformation rules and generating an output message, where the content of the output message is re-formatted according to a second set of formatting rules allowed under the medical electronic communication protocol. The transformation rules can control the re-formatting of the content of the output message so as to comply with the second set of formatting rules. The method can also include outputting the output message to a medical device.

In various embodiments, a method of providing field-customizable transformation of input and output medical messages belonging to a common medical electronic communication protocol but having different formats includes receiving an input message from a first medical device, the content of the input message being formatted according to a first set of formatting rules. The method can further include determining an intended recipient medical device from the input message. The method can also include comparing the input message to a set of transformation rules and changing the formatting of the input message to reflect a second set of formatting rules expected by the intended recipient medical device based on the comparison of the input message to the set of transformation rules. Moreover, the method can also include generating an output message, the content of the output message being formatted according to the second set of formatting rules, and outputting the output message to the intended recipient medical device.

In certain embodiments, a system for facilitating communication of medical messages between a hospital information system and a patient monitor includes a hospital information system having an electronic medical records database configured to store electronic medical records of patients. The system can further include a patient monitor configured to monitor at least one physiological condition of a patient. The system can also include a transformation module configured to be communicatively coupled between the hospital information system and the patient monitor. The transformation module can be configured to receive an input message from one of the hospital information system or the patient monitor, the content of the input message being formatted according to a first set of formatting rules; compare the input message to a set of transformation rules; and generate an output message, the content of the output message being re-formatted according to a second set of formatting rules, where the transformation rules control the re-formatting of the content of the output message so as to comply with the second set of formatting rules.

In certain embodiments, a system for facilitating communication of medical messages between medical devices over a network includes a first medical device configured to transmit and receive medical messages, the first medical device configured to be communicatively coupled to a network. The system can further include a second medical device configured to transmit and receive medical messages, the second medical device configured to be communicatively coupled to the network. The system can also include a transformation module configured to be communicatively coupled between the first medical device and the second medical device. The transformation module can be configured to receive an input message from the first medical device, where the content of the input message is formatted according to a first set of formatting rules, and to compare the input message to a set of transformation rules. The transformation module can also be configured to generate an output message, where the content of the output message is re-formatted according to a second set of formatting rules, and where the transformation rules control the re-formatting of the content of the output message so as to comply with the second set of formatting rules. Moreover, the transformation module can be configured to output the output message to the second medical device.

In various embodiments, a method of defining formatting of medical communications under a medical electronic communication protocol includes compiling format transformation software, installing the format transformation software, and updating a set of transformation rules within a user-configurable file without recompiling the format transformation software.

In certain embodiments, a method for analyzing physiological parameter monitoring data includes receiving physiological parameter data from multiple patients. The method can further include receiving first physiological parameter alarm data from the patients that is indicative of

alarm conditions experienced by the patients that were detected based upon a first alarm criteria. The method can also include generating second physiological parameter alarm data using a processor, where the second physiological parameter alarm data is indicative of simulated alarm conditions that are detected based upon a second alarm criteria. Moreover, the method can include comparing the first and second physiological parameter alarm data using a processor. In certain embodiments, a computer-readable medium includes instructions that, when read by a computer, cause the computer to perform this method for analyzing physiological parameter monitoring data.

In various embodiments, a method for analyzing physiological parameter monitoring data includes receiving physiological parameter data from multiple patients. The method can further include receiving first physiological parameter alarm notification data indicative of physiological parameter alarm notifications generated based upon a first alarm notification delay time. The method can also include generating second physiological parameter alarm notification data using a processor, where the second physiological parameter alarm notification data is indicative of simulated physiological parameter alarm notifications generated based upon a second alarm notification delay time. Moreover, the method can include comparing the first and second physiological parameter alarm notification data.

BRIEF DESCRIPTION OF THE DRAWINGS

Various embodiments will be described hereinafter with reference to the accompanying drawings. These embodiments are illustrated and described by example only, and are not intended to limit the scope of the disclosure.

FIG. **1** is an exemplary block diagram showing a physiological monitoring system according to an embodiment of the present invention;

FIG. **2** is an exemplary block diagram showing another embodiment of a physiological monitoring system;

FIG. **3** is an exemplary block diagram showing a network interface module according to an embodiment of the present invention;

FIG. **4** is an exemplary flowchart diagram showing a process for context-based communication of physiological information according to an embodiment of the present invention; and

FIG. **5** is an exemplary block diagram showing an alarm notification system according to an embodiment of the present invention.

FIG. **6** is a block diagram illustrating an embodiment of a clinical network environment;

FIG. **7** is a block diagram illustrating a more detailed embodiment of the clinical network environment of FIG. **6**;

FIG. **8**A is a flow chart illustrating an embodiment of a process for journaling medical events in a journal database;

FIG. **8**B is a flow chart illustrating an embodiment of a process for correlating data from the journal database and the round-robin database;

FIG. **9** is a screen shot of an example user interface for monitoring patients in the clinical network environment of FIG. **6**;

FIG. **10** is a perspective view of an advanced patient-monitoring system;

FIG. **11** illustrates a proximity display in a multi-user environment;

FIG. **12** is a general block diagram of a proximity display monitor;

FIG. **13** illustrates a user display preference screen;

FIG. **14** is a schematic diagram of a patient monitoring device that is capable of automatically detecting the presence of a clinician token;

FIG. **15** is a flowchart illustrating detection method for detecting the presence of a clinician token within the detection region of a patient monitoring device;

FIG. **16** illustrates an example graphical user interface of nurses' station or a central patient monitoring station;

FIG. **17** is a flowchart illustrating a method for determining when to disable a clinician-specific action that had been previously enabled by a patient monitoring device based upon the detected presence of the clinician;

FIG. **18** is a schematic diagram of a system for enabling a patient monitoring device to automatically detect the presence of a clinician token;

FIG. **19** is a schematic illustration of a patient monitoring device network having a clinician proximity awareness feature;

FIG. **20** is a schematic drawing of a hospital floor with distributed WiFi access points that can be used to estimate the physical locations of medical devices, patients, and clinicians;

FIGS. **21**A-F, FIGS. **22**A-E, and FIGS. **23**A-C illustrate proximity display embodiments that advantageously provide user proximity feedback;

FIGS. **21**A-F illustrate a proximity display embodiment utilizing a virtual rotating triangular solid for proximity feedback;

FIGS. **22**A-E illustrate a proximity display embodiment utilizing a virtual rotating cube for proximity feedback;

FIGS. **23**A-C illustrate proximity display embodiment utilizing a virtual rotating planar solid for proximity feedback;

FIG. **24**A illustrates a first medical device and a second medical device that communicate with one another via a translation module;

FIG. **24**B illustrates a first medical device and a second medical device that communicate with one another via a translation module and a communication bus;

FIG. **25**A illustrates an example input message received by the translation module;

FIG. **25**B illustrates a message header segment of the input message of FIG. **19**A that has been parsed into fields;

FIG. **25**C illustrates an encoded version of the parsed message header segment of FIG. **25**B;

FIG. **25**D illustrates an example output message of the translation module based on the input message of FIG. **25**A;

FIG. **26** illustrates a translation process for generating an output message based on an input message and a comparison with translation rules associated with the translation module;

FIG. **27**A illustrates a translation process in which the translation module facilitates communication of an HL7 message from a Hospital Information System ("HIS") having a first HL7 format to an intended recipient medical device having a second HL7 format;

FIG. **27**B illustrates a translation process in which the translation module facilitates communication of an HL7 message from a medical device having a first HL7 format to a HIS having a second HL7 format;

FIG. **28** illustrates an example screenshot from a messaging implementation software tool for manually configuring translation rules to be used by the translation module;

FIGS. **29**A and **29**B illustrate automatic rule configuration processes performed by the translation module;

FIGS. **29**C and **29**D illustrate automatic rule configuration processes performed by the translation module for messages utilizing the HL7 protocol;

FIG. **30** is an example graph of the distribution of alarm events for a given physiological parameter as a function of alarm limit values;

FIG. **31** is a flow chart that illustrates a method for determining the variation in identified alarm conditions resulting from varying alarm criteria;

FIG. **32** illustrates an example report with a table showing how simulated alarm criteria affect alarm detection events;

FIG. **33** is a flow chart that illustrates another method for determining the variation in identified alarm conditions that occur as a result of varying alarm criteria;

FIG. **34** illustrates an example report with a table showing how simulated alarm criteria affect the number of alarm detection events as well as how the simulated alarm criteria affect, for example, false negatives and false positives;

FIG. **35** is a flow chart that illustrates a method for determining the variation in alarm notification events that occurs as a result of varying alarm notification delay times;

FIGS. **36**A-B, FIGS. **37**A-F, FIGS. **38**A-B, FIGS. **39**A-B, FIGS. **40**A-B, FIG. **41**, FIG. **42**, and FIGS. **43**A-B illustrate proximity displays that provide advantageous features in multi-user patient-monitoring environment;

FIGS. **36**A-B illustrate displays having layout zones;

FIGS. **37**A-F illustrate displays that vary layouts and font sizes according to the number of installed parameters;

FIGS. **38**A-B illustrate displays having parameter wells;

FIGS. **39**A-B illustrate displays that enlarge alarming parameters;

FIGS. **40**A-B illustrates displays of trend graphs having colored alarm zones;

FIG. **41** illustrate a display that inverts arrow keys to match the cursor;

FIG. **42** illustrates a display having user-selectable jump-screens; and

FIGS. **43**A-B illustrate trend graph displays.

DETAILED DESCRIPTION

In various embodiments, physiological monitoring systems are systems that monitor physiological signals generated by a medical patient and process the signals to determine any of a variety of physiological parameters of the patient. For example, in some cases, a physiological monitoring system can determine any of a variety of physiological parameters of a patient, including respiratory rate, inspiratory time, expiratory time, i:e ratio (e.g., inspiration-to-expiration ratio), inspiratory flow, expiratory flow, tidal volume, minute volume, apnea duration, breath sounds, rales, rhonchi, stridor, and changes in breath sounds such as decreased volume or change in airflow. In addition, in some cases the physiological monitoring system monitors other physiological sounds, such as heart rate to help with probe-off detection, heart sounds (e.g., S1, S2, S3, S4, and murmurs), and changes in heart sounds such as normal to murmur or split heart sounds indicating fluid overload. Moreover, the physiological monitoring system may use a second probe over the chest for better heart sound detection, keep the user inputs to a minimum (for example, only input height), and use a Health Level 7 (HL7) interface to automatically input demography.

A physiological monitoring system of certain embodiments includes one or more patient monitoring devices connected to a shared network using open architecture communications standards. The patient monitoring devices of certain embodiments include a physiological monitor coupled with a network interface module. The physiological monitor includes one or more sensors and a sensor processing module for processing signals from the sensors. The network interface module receives physiological information from the sensor processing module and transmits this information over the shared network. The network interface module may connect to a variety of physiological monitors. In addition, the network interface module of various implementations is a portable bedside device assigned exclusively to one medical patient.

In certain embodiments, the network interface module facilitates establishing a network connection directly with end users over the shared network. These end users, including doctors, nurses, and other hospital staff, may receive physiological information, alarms, and alerts from the network interface module on an electronic device, such as a pager, PDA, laptop, computer, computer on wheels (COW), or the like.

Referring to FIG. **1**, certain embodiments of a physiological monitoring system **100** (e.g., alarm notification system) include an open network architecture using "off-the-shelf" hardware and communication protocols. This architecture in various implementations is a shared, or open, network includes multiple patient monitoring devices **110**, a network bus **120** (e.g., an Ethernet backbone), and a hospital WLAN **126**. In addition, the shared network may further include a connection **122** to the Internet **150**, to end user devices **152** over the Internet **150**, and to end user devices **128** over the hospital WLAN **126**. The physiological monitoring system **100** of certain embodiments is therefore an enterprise system that achieves a cost-effective replacement for currently available patient monitoring systems.

The physiological monitoring system **100** includes a plurality of bedside devices, e.g., patient monitoring devices **110**. The patient monitoring devices **110** of various embodiments include sensors **102**, one or more sensor processing modules **104**, and a communications module, e.g., network interface module **106**. In the depicted embodiment, two patient monitoring devices **110** are shown. One patient monitoring device includes one set of sensors **102**, one sensor processing module **104**, and one network interface module **106**. The other patient monitoring device **110** includes two sets of sensors **102**, two sensor processing modules **104**, and one network interface module **106**.

In certain embodiments, each patient monitoring device **110** is used by one medical patient. The patient monitoring devices **110** form a network of patient monitoring devices **110**, each of which can communicate with clinicians and other end users over a shared network, including a hospital network **126** and network interfaces to the Internet **150**.

One or more sensors **102** of the patient monitoring device **110** are attached to a medical patient. These sensors **102** may include ECG sensors, acoustic sensors, pulse oximeters, and other types of sensors. The sensors **102** obtain physiological information from a medical patient and transmit this information to the sensor processing module **104** through cables **103** or through a wireless connection (not shown). In certain embodiments, the physiological information includes one or more physiological parameters or values and waveforms corresponding to the physiological parameters.

The sensor processing module **104** receives physiological information from the sensors **102**. The sensor processing module **104** of certain embodiments includes a circuit having a processor, input ports for receiving the physiological information, software for processing the physiological information in the processor, an optional display, and optionally an input device (e.g., a keyboard). In addition, the sensor processing module **104** contains one or more output ports, such as serial ports. For example, an RS232, RS423, or

autobaud RS232 (serial interface standard) port or a universal serial bus (USB) port may be included in the sensor processing module **104**.

In certain embodiments, the sensor processing module **104** generates waveforms from signals received from the sensors **102**. The sensor processing module **104** may also analyze single or multiparameter trends to provide early warning alerts to clinicians prior to an alarm event. In addition, the sensor processing module **104** in certain embodiments generates alarms in response to physiological parameters exceeding certain safe thresholds.

Example alerts include no communication with pulse oximeter, alarm silenced on pulse oximeter, instrument low battery (pulse oximeter), and transmitter low battery. Example alarms include SpO_2 levels and alarms, high and low SpO_2, high and low PR, HbCO level and alarms, HbMET level and alarms, pulse rate and alarms, no sensor, sensor off patient, sensor error, low perfusion index, low signal quality, HbCO, HbMET, PI trend alarm, and desat index alarm.

The network interface module **106** in the depicted embodiment is connected to one or more sensor processing modules **104** through one or more connectors **108**, which may be serial connectors corresponding to the serial ports in the sensor processing modules **104**. Dashed lines on the connector **108** indicate that the network interface module **106** of certain embodiments is not permanently attached to the sensor processing modules **104**. In alternative embodiments (not shown), however, the network interface module **106** is contained within a sensor processing module **104**.

The network interface module **106** in various implementations includes a processor, an input port (such as a standard RS232 serial port), a network output port such as an Ethernet port, and software which enables the network interface module **106** to act as a network-communications enabled device. In addition, the network interface module **106** includes a storage device **114**, which may be included within the network interface module **106** or attached separately to the network interface module **106**.

The network interface module **106** manages the connectivity overhead for initiating and maintain connectivity with end user devices over the shared network. In certain embodiments, the network interface module **106** manages connectivity by acting as a microserver or web server. In such instances, the network interface module **106** is a network connection enabled device. As a web server, the network interface module **106** establishes direct connections to the Internet **150**, such that an end user may access web pages stored on the storage device **114** of the network interface module **106**. In one embodiment, the network interface module **106** therefore does not require a separate server for connecting to the Internet **150**. In one embodiment, the network interface module **106** connects to the Internet **150** directly through a modem, such that the connection **122** includes a modem. In managing connectivity over the shared network, the network interface module **106** may also perform security management functions, such as user authentication.

In certain embodiments, the network interface module **106** sends data over the shared network through an access point **124** or other wireless or wired transmitter. Alternatively, the network interface module **106** may communicate physiological information directly to end users over the Internet **150**. End users such as clinicians carrying notifier devices, e.g., end user devices **128**, **152** connected to the hospital WLAN **126** may receive real-time viewing of physiological patient parameters and waveforms on demand or in the event of an alarm or alert. Real-time or slightly delayed transmission of physiological information in certain embodiments comports with standards for alarm latency in compliance with Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards for effective alarm response. The network interface module **106** of certain embodiments therefore adds functionality equivalent to a central nurses' station.

In certain embodiments, the network interface module **106** performs context management. In one embodiment, context management includes associating context information with physiological information to form a contextual data package. Context information may include several categories of information, including the categories of context information related to the network interface module **106**, context information related to the medical patient, context information related to usage of the network interface module **106**, and context information related to a network connection. Within one or more of these context categories, context information might include a patient name, a patients' unique hospital identification number, patient location, an identification number for a network interface module **106**, time stamps for events occurring in the physiological monitoring system **100**, environmental conditions such as changes to the state of the network and usage statistics of the network interface module **106**, and identification information corresponding to the network link (e.g., whether the network connection is WiFi or Ethernet). In one embodiment, the context information in the contextual data package may include all of or any subset of context information from one or more of the context categories.

The network interface module **106** receives context information, for example, by a nurse entering the information in the network interface module **106** or from a server **136**. In one embodiment, by receiving this information (including, e.g., patient identification number and location), the network interface module **106** becomes exclusively assigned to the medical patient. The network interface module **106** transmits or communicates the contextual data package to clinicians during an alarm or alert, upon clinician request, or on a scheduled basis. In addition, the network interface module **106** may transmit a continuous stream of physiological information to clinicians.

By optionally connecting to multiple sensor processing modules **104** in certain embodiments, the network interface module **106** is able to associate patient context information and other context information with multiple sensor processing modules **104**. Consequently, context can be created for one or more sensor processing modules **104** in addition to context being created for the network interface module **106**.

In addition to transmitting the contextual data package, the network interface module **106** in one embodiment stores the contextual data package in the storage device **114**. The storage device **114** may be a flash memory, a hard disk drive, or other form of non-volatile or volatile memory. In certain embodiments the storage device **114** acts as a flow control buffer. The network interface module **106** uses the storage device **114** acting as a flow control buffer to perform flow control during communications, as explained more fully below in connection with FIG. **3**.

In some implementations, a server **136** may optionally be included in the physiological monitoring system **100**. The server **136** in these implementations is generally a computing device such as a blade server or the like. In certain embodiments, the server **136** is an appliance server housed

in a data closet. In other embodiments, the server **136** is a server located at a central nurses' station, such as a workstation server.

The server **136** receives contextual data packages from a plurality of network interface modules **106** and stores the contextual data package in a storage device **138**. In certain embodiments, this storage device **138** therefore archives long-term patient data. This patient data may be maintained even after the patient is discharged. In storing patient data, the server **136** may act as an interface between the shared network and an external electronic medical record (EMR) system.

The server **136** may also store data concerning user interactions with the system and system performance metrics. Integrated into the server **136** of certain embodiments is a journal database that stores every alert and alarm or a subset of the alerts and alarms as well as human interaction in much the same way as an aviation "black box" records cockpit activity. The journal is not normally accessible to the clinical end user and, without technical authorization, cannot be tampered with. In addition, the server **136** may perform internal journaling of system performance metrics such as overall system uptime.

In one embodiment, the journaling function of the server **136** constitutes a transaction-based architecture. Certain transactions of the physiological monitoring system **100** are journaled such that a timeline of recorded events may later be re-constructed to evaluate the quality of healthcare given. These transactions include state changes relating to physiological information from the patient monitoring devices **100**, to the patient monitoring devices **110**, to the hospital WLAN **126** connection, to user operation, and to system behavior. Journaling related to the physiological information received from a physiological monitor in one embodiment includes recording the physiological information itself, recording changes in the physiological information, or both.

The server **136** in certain embodiments provides logic and management tools to maintain connectivity between network interface modules **106**, clinician notification devices such as PDAs and pagers, and external systems such as EMRs. The server **136** of certain embodiments also provides a web based interface to allow installation (provisioning) of software rated to the physiological monitoring system **100**, adding new devices to the system, assigning notifiers (e.g., PDAs, pagers, and the like) to individual clinicians for alarm notification at beginning and end of shift, escalation algorithms in cases where a primary caregiver does not respond to an alarm, interfaces to provide management reporting on the alarm occurrence and response time, location management, and internal journaling of system performance metrics such as overall system uptime (see, e.g., FIG. **5** and accompanying description).

The server **136** in certain embodiments also provides a platform for advanced rules engines and signal processing algorithms that provide early alerts in anticipation of a clinical alarm. The operating system on the server **136** in one embodiment is Linux-based for cost reasons, though a Microsoft-based or other operating system may also be used. Moreover, the server **136** is expandable to include data storage devices and system redundancy capabilities such as RAID (random array of independent disks) and High Availability options.

In another embodiment (not shown), end user devices **128**, **152** include one way POCSAG Pagers having a 2 line display with audible and vibrate mode, of suitable size and durability for severe mechanical environments typical of hospital general floor settings. In yet another embodiment, the end user devices **128**, **152** include two way paging systems, such as Motorola Flex and WLAN pagers. One advantage of two-way paging is the ability to confirm message receipt and the ability to remotely silence alarms. Wireless PDAs may also be used by end users based on ruggedness and acceptable form factors as determined by an end user. An example of such a device is the Symbol Technology MC50 PDA/Barcode Scanner.

FIG. **2** depicts another embodiment of the physiological monitoring system **200** of the present invention. The physiological monitoring system **200** includes network communications enabled devices **210**. The network communications enabled devices **210** are connected directly to a hospital network **220** through a wireless connection. In certain embodiments, the network communications enabled devices **210** include sensors and sensor processing modules, similar to the sensors **102** and sensor processing modules **104** of FIG. **1**. Certain of these network communications enabled devices **210** are bedside devices, and others are handheld or otherwise patient-worn devices that may be used by an ambulatory (mobile) patient.

The hospital network **220** transmits physiological information and context information to clinician notifier devices, including pagers **240**, PDAs **230**, and the like. In certain embodiments, the hospital network **220** utilizes a server **250** to transmit contextual data packages to a page transmitter **242**, which further transmits the data to one-way wireless pagers **240**. An external interface **280** may be coupled with the server **250**. The external interface **280** could include one or more of the following: enterprise paging, nurse call systems, wide area paging systems, enterprise clinical and patient information systems, and third party monitoring and surveillance systems.

Certain other devices **260**, such as some patient monitoring equipment, are not network communications enabled devices. That is, these other devices **260** are unable to connect to a network unaided. In the depicted physiological monitoring system **200**, example devices **260** that are not network communications enabled are connected to a network interface module **270**. The network interface module **270** is connected to the non-network communication enabled other devices **260** through RS232 cables **264**. Such a connection is a standardized serial connection found on many devices. Because the network interface module **270** has an RS232 port, the network interface module **270** can allow non-network communication enabled patient monitoring devices to connect directly to the hospital network **220** and also to the Internet.

Moreover, by connecting to one or more other devices **260** in some embodiments, the network interface module **270** is able to associate patient context information and other context information with one or more other devices **260**. Consequently, context can be created for one or more other devices **260** in addition to context being created for the network interface module **270**.

FIG. **3** depicts a network interface module **300** in accordance with certain embodiments of the present invention. The network interface module **300** in the depicted embodiment includes an input port **302**, which in certain embodiments is a serial port for facilitating a connection to a sensor processing module. The network interface module **300** also includes a network interface **304**, which may be a wired interface (e.g., Ethernet) or a wireless interface such as WiFi, Bluetooth, or the like. Alternatively, the network interface module **104** may communicate through a cable TV interface or other type of interface. Such a CTV interface provides a

subcarrier bi-directional communications capability that would simultaneously co-exist with video formats.

The network interface module **300** also communicates with a storage device **350**. While in the depicted embodiment the storage device **350** is shown as separate from the network interface module **300**, in some implementations the storage device **350** is part of the network interface module **300**. In addition, though not shown, the network interface module **300** may include a processor for implementing communications program code. Similarly, though not shown, the network interface module **300** may include an input device for a nurse to input context information and a display for receiving output from the network interface module **300**.

The network interface module **300** can be integrated into handheld, portable or stationary patient monitoring platforms or instruments or contained in an accessory package with an RS232 input for general interface to such devices. In another embodiment, (not shown) active RFID tag capabilities are included with the network interface module **106**, with the clinician devices (e.g., notifier devices), or with both so that either a patient or a clinician can be located when an event occurs or on request. When operating on a shared network, the network interface module **106** is also compliant with to the open architecture communications standards of IEEE 802.1X (security and authorization), IEEE 802.3 (Ethernet), and WiFi (IEEE 802.11 a, b, g, e, i wireless protocols).

A context management module **310** in the network interface module **300** manages context data. In one embodiment, the context management module **310** receives context information, such as the context information described in connection with FIG. **1** above. In one embodiment, a nurse or other clinician enters context information, such as patient name, identification number, and location, into the network interface module **300** via a keyboard or other input device (not shown) when the patient is admitted to the hospital or assigned a particular bed in the hospital. In other embodiments, the context management module **310** receives the context information from a server, such as the server **136** of FIG. **1**.

The context management module **310** associates the context information with physiological information received from a sensor processing module. In certain embodiments, the context management module **310** performs this association when an alarm condition occurs. In such instances, the context management module **310** may create a contextual data package including a snapshot of historical physiological information together with the context information. In other embodiments, the context management module **310** performs an association continuously, and the network interface module **300** sends continuous or scheduled contextual data packages to end users. In addition, the context management module **310** or other modules in the network interface module **300** store the contextual data package in the storage device **350**.

The communications module **320** uses the network interface **304** to communicate with a network. In certain embodiments, the communications module **320** possesses the functionality of a web server. As a web server, the communications module **320** enables the network interface module **300** to communicate with a hospital network and the Internet directly, without using a server. Consequently, other devices such as physiological monitoring devices that are not network connection enabled may connect with the network interface module and thereby become network enabled. The network interface module **300** manages the connectivity overhead for initiating and maintaining connectivity, manages context information (e.g., any of the context information described above in connection with FIG. **1**), and provides a web server for displaying patient information on web-enabled devices. In one embodiment, a communications protocol based on XML technologies allows bedside devices to interface to a multitude of target end user platforms including PDAs, computer on wheels (COW), Tablet PCs, IP cell phones (smartphones), and fixed PCs.

In certain embodiments, the communications module **320** uses standard communications protocols to communicate with a network. Some examples of standard communications protocols include Ethernet, WiFi (WLAN), Bluetooth, and the like. By using standard communications protocols, the communications module **320** is able to send and receive data over a shared network or open network architecture. However, the communications module **320** may also be used on a proprietary network using proprietary protocols.

In embodiments where the network interface module **300** communicates over a shared network rather than a proprietary network, the network interface module **300** shares network resources with other devices on the network. In some cases, high-volume network traffic affects the reliability of network communications. Consequently, certain implementations of the network interface module **300** include a flow control module **330**. The flow control module **330** verifies that transmitted data was received by an end user. In the event that the end user did not receive the data, the flow control module **330** resends the data stored in the storage device **350**. In certain embodiments, the storage device **350** therefore acts as a flow control buffer.

A security module **340** manages user access to the network interface device **300** and to data stored in the storage device **350**. In certain embodiments, the security module **340** determines whether a user attempting to connect to the network interface module **300** is authorized to do so. In one implementation, the security module **340** uses the standard IEEE.802.1X network access control protocol to manage authentication. The network interface module **106** in certain embodiments provides security and encryption to meet the Health Insurance Portability and Accountability Act (HIPAA) requirements.

In certain embodiments, the network interface module **300** incorporates all or a portion of the functionality specified by the IEEE 1073 standard and the most recent update to the IEEE 1073 standard, namely the IEEE 11703 standard, both of which are hereby incorporated by reference. In certain embodiments, the context management module **310**, the communications module **320**, the flow control module **330**, and the security module **340** also incorporate functionality specified in the IEEE 1073 and **11703** standards. By using standard protocols, the network interface module **300** may be used to enable network communication for a wide variety of physiological monitoring devices.

FIG. **4** depicts a process **400** for context-based communication of physiological information according to an embodiment of the present invention. In certain embodiments, the process **400** is performed by any of the network interface modules described above in connection with FIGS. **1-3**. In addition, the process **400** in certain embodiments may be performed by any of the physiological monitoring systems described in connection with FIGS. **1**, **2**, and **5**.

The process **400** begins by receiving context information at **402**. In one embodiment, a device such as a network interface module receives the context information once, such as in an initialization step. The process **400** then

receives physiological information at **404**. In certain embodiments, the process **400** continues to receive physiological information throughout the remaining steps of the process **400**. Alternatively, the process **400** may receive physiological information **400** for a portion of the process **400**.

At **405**, the process **400** determines whether an alarm condition or alert has occurred. If an alarm condition or alert has occurred, the process **400** proceeds to **406**. However, if an alarm condition or alert has not occurred, the process **400** loops back to **404**. In one embodiment, the looping back of the process **400** to **404** represents that a network interface module continually receives physiological information until an alarm condition or alert occurs. In certain embodiments (not shown), the process **400** may continue to receive physiological information even when an alarm condition or alert occurs.

At **406** the process **400** prepares a contextual data package. The contextual data package may include context information and a snapshot of physiological information. In one embodiment, the snapshot of physiological information includes the physiological information that gave rise to an alarm or alert. In one embodiment, the snapshot of physiological information includes information both before and after the occurrence of an alarm or alert. The contextual data package is stored in a flow control buffer at **408**.

At **410**, the process **400** establishes a network connection. In one embodiment, establishing a network connection at **410** includes connecting a network interface module to an end user device, such as a notifier device assigned to a nurse during his or her work shift. The process **400** then determines at **412** whether the user of the device (e.g., the nurse) has been authenticated. If the user has not been authenticated, the process **400** proceeds to **420**. On the other hand, if the user has been authenticated, the process **400** proceeds to **414**.

The process **400** at **414** communicates the contextual data package to the user. At **416**, the process **400** determines whether the contextual data package was received. If the contextual data package was received, the process **400** proceeds to **420**. Otherwise, the process **400** proceeds to **418**, where the process **400** accesses data stored in the flow control buffer. In one embodiment, the data accessed by the process **400** is equivalent to or substantially equivalent to the contextual data package communicated to the user at **414**.

The process **400** then loops back to **414**, where the process **400** communicates (e.g., resends) the contextual data package to the user, and then at **416** re-verifies that the package was received. The process **400** in some implementations continues to loop between steps **414**, **416**, and **418** until the contextual data package was received. Thus, steps **414**, **416**, and **418** in certain embodiments constitute flow control performed by the process **400**. These flow control steps allow the process **400** to overcome network transmission errors which may occur in shared networks.

If the contextual data package was received, the process **400** evaluates whether to continue the monitoring of physiological information at **420**. If the process **400** determines to continue monitoring, the process loops back to **404**, where the process **400** continues to receive physiological information. If, however, the process **400** determines not to continue monitoring, the process **400** ends.

In various embodiments of the process **400**, the contextual data package or the physiological information alone is transmitted to the user even in the absence of an alarm condition. In still other embodiments, fewer than all of the steps are performed, or the steps are performed in different order. For instance, the process **400** may only perform the steps of receiving physiological information at **404**, preparing a contextual data package at **406**, establishing a network connection at **410**, and communicating the contextual data package to the user at **414**.

FIG. **5** depicts an alarm notification system **500** in accordance with certain embodiments of the present invention. A clinical subsystem **510** defines the major software components of alarm notification system **500** including a clinical assignment module **512**, a bedside device initialization module **514**, a notification and viewing module **516**, an escalation rules module **518**, a clinical report module **520**, and a clinical data stores module **522**. An authentication feature is built into mobile computing devices in compliance with HIPAA and hospital IT policies.

The clinical assignment module **512** has an assignment function. A nursing supervisor assigns individual nurses to specific patients at the start of each shift and upon admission of new patients. Shift assignments take place at change of shift during a "report" transition exercise where individual nurses and nursing supervisor from previous shift "hand off" patients to the next shift. The report can be either formal where all nurses attend or informal dependent on hospital nursing service policies and procedures. The clinical assignment module **512** provides an intuitive interface that allows a listing of available nurses to be assigned individual patients. The major user of this module is the unit clerk as assigned by the nursing supervisor. A nurse can be assigned one or more patients or all patients. An alternative work flow is self assignment where individual nurses assign patients themselves in which case they perform functions of the unit clerk. In the self assignment model, a default is implemented where any unassigned patient is either assigned to all nurses or the nursing supervisor.

The bedside device initialization module **514** has bedside devices, such as the network interface modules described above, that are sometimes set up by an aide to the nurse. In the case where the nurse performs this task, she or he performs the functions of the nursing aide. Work flow includes delivering a device to bedside, applying sensors, initializing the device, and setting patient context, such as name, ID and location.

The notification and viewing module **516** assigns a wireless notification device, such as a one-way pager, PDA, IP telephone, COW, or Tablet to individual nurses. The device becomes associated with her or him. Alarms are routed to the notification device based on the clinical assignment module **512**. Non-dedicated notifier solutions such as hospital owned paging systems issued to nurses have unknown latency characteristics. A general purpose interface is available at the server with a latency of less than 1 second upon receipt from the bedside device and is time stamped upon presentation to the server external interface and stored in a journaling system within the server. An additional interface for mobile computing platforms such as PDA, COWS, and Tablets allows viewing of current and trend data for an individual patient.

The escalation rules module **518** has a rules engine that actuates an escalation policy defined by the hospital. The escalation rules module **518** provides alternative routing of alarms to alternative and additional clinical users in the event an alarm is not responded to or persists for a predefined (e.g., by a policy) period of time. The escalation rules module **518** in certain embodiments routes alarms to an emergency response team.

The clinical report module **520** provides predefined formatted reports on the clinical data from which to determine

physiologic condition and/or progress. More than one report may be dependent on end user needs. Reports are not time critical views of individual patients and may be remotely viewed by clinicians who have alarm notification system **500** privileges and have been authenticated by the alarm notification system **500**. These reports are web browser views that allow clinicians to set viewing parameters such as time and parameter scales and alarm review.

The clinical data stores module **522** provides data storage and database resources to store information as known to those skilled in the art.

Further shown in FIG. **5**, a technical support subsystem **530** is isolated from the clinical subsystem **510** in compliance with HIPAA and as such does not allow viewing or access to any patient information with the exception of the risk report module **538**. The technical support subsystem **530** includes a provisioning module **532**, an administration module, a service module **536**, a risk report module **538**, and a technical data store module **540**.

The provisioning module **532** provides provisioning, which is the initial installation of the system and first customer use. The primary user of the provisioning module **532** is the field installer. The provisioning module **532** contains all the start up scripts and system configurations to bring the system from shipping boxes to full alarm notification system **500** functionality. Provisioning includes steps to configure individual devices, notifiers such as pagers, PDA, COW, Tables and IP telephone at the customer site, preferably by wireless means (e.g., Bluetooth).

The administrative module **534** provides a system interface for the application administrator to set up users, set policies for various actor privileges such as a nurses aide being able to set or change alarms, set up allowed device connection identifications, and other general systems administrative duties typical of IT systems.

The service module **536** provides interfaces for various technical support actors including remote service, IT Service, and Biomed Service. Each of these actors may perform each others' functions. Interfaces allow the service actors to access system performance data to access performance, for example, data traffic, device assets connected, software version management, CPU loading, network loading, etc. and execute remote technical service procedures, for example, resetting a printer queue, repartition of disk, uploading software patches, etc. The service module **536** includes a full journaling function that stores every user interaction or a portion of user actions that can be captured by the system, especially changes in default values or alarm settings.

The risk report module **538** provides summary reports on alarm occurrences, duration of alarm, clinical response time to alarms and other statistical data to determine overall effectiveness of clinical response to alarms in compliance with JCAHO, other regulatory bodies, and internal quality assurance committees.

The technical data stores module **540** has the same characteristics as the clinical data stores module **522** except that the technical data stores module **540** is used for technical data. The technical data stores module **540** may or may not share the same physical and logical entity as the clinical data stores module **522**.

Additionally shown in FIG. **5**, an external interface subsystem **550** provides interfaces to bedside devices and external systems such as electronic medical records, admit discharge, transfer systems, POCSAG pager systems, middleware engines such as Emergin, and Web/XML enabled devices such as wireless PDAs, COWs and Tablet PCs. The external interface subsystem **550** has an HL7 interface **552**, a pager interface **554**, an XML/Web interface **556**, and a device interface **558**.

The HL7 interface **552** provides a bi-directional interface to electronic medical records (EMR) and supports both push and pull models. The push model is when a bedside nurse initiates data transfer. The pull model is when an EMR system polls the alarm notification system **500** server. The pager interface **554** provides output to external paging system. Message latency is identified to an end user for any user-owned paging solution. This same output can be used for middleware alarm notification systems such as Emergin. The XML/Web interface **556** provides bi-directional interface with mobile computing platforms such as wireless PDA, COWs, Tables, and Web-enabled IP phones. Mobile computing platforms support Web Browser XML applications. The device interface **558** provides a bi-directional interface to bedside devices as well as to other devices enabled by the communications module or accessory. Application Programmer Interface (API) capability is an option for interfacing to other bedside devices.

The major end users of the alarm notification system **500** system (not shown or described for simplicity) include hospital electronic medical records, admit discharge transfer, pharmacy, clinical information, patient flow tracking and others. Actors, e.g., users of the alarm notification system **500**, including clinical actors and technical support actors. The clinical actors include nursing supervisors, unit clerks, nursing aides, nurses, rapid response teams and respiratory therapists.

A nursing supervisor assigns individual nurses to specific patients at the beginning of each shift. Shift can vary according to hospital staffing policies. A unit clerk takes direction from the nursing supervisor, typically inputs assignments into system and monitors overall system. A unit clerk may not be available for all shifts. A nursing aide takes assignments from nurse or nursing supervisor, typically applies bedside device sensor, initializes the bedside device and sets alarms to default values. A nurse has primary responsibility for individual patient care and primary response to alarms. The nurse is assigned by nursing supervisor to more than one patient dependent on her/his skills and patient needs and is not always assigned the same patient. Nursing aides are not found in all hospitals.

A rapid response team responds to clinical emergencies initiated by either a bedside nurse or a nursing supervisor. The team supports more than one care unit and has one or more members depending on shift. Rapid Response Teams may not be implemented in all hospitals. A respiratory therapist has responsibilities for management of respiratory care for more than one patient and usually more than one care unit. Respiratory therapists are not found in some international settings.

Clinical actor performance substitution allows a high capability actor to assume the roles of other actors. Alarm notification system **500** allows mechanisms for such performance. For example, a nursing supervisor may perform functions of a unit clerk nursing aide, a nurse and a rapid response team. A nurse may perform functions of a unit clerk, a nursing aide and a rapid response team. In some international markets a nurse may perform the functions of a respiratory therapist.

The technical support actors include field installers, application administrators, remote services, IT engineers, biomedical engineers and risk managers. A field installer provisions the system for initial installation, installs components, and validates that the installation and configu-

ration meet a purchasing contract. An application administrator sets up and maintains user accounts and systems defaults. A remote service provides remote diagnostics and system maintenance over a remote link, such as dial up and VPN. An IT engineer provides network support services if the system is integrated with the hospital IT network. A biomedical engineer provides bedside and system primary service. A risk manager reviews reports for quality and risk mitigation purposes. Technical support actors may also fill in for other actors. For example, an IT engineer, a biomedical engineer, or a remote service can perform the functions of an application administrator. An IT engineer or a biomedical engineer can perform each other's functions.

In certain embodiments, systems and methods are provided for rapidly storing and acquiring physiological trend data. For instance, physiological information obtained from a medical patient can be stored in a round-robin database. The round-robin database can store the physiological information in a series of records equally spaced in time. Parameter descriptors may be used to identify parameter values in the records. The parameter values can be dynamically updated by changing the parameter descriptors to provide for a flexible database. In addition, the size of files used in the database can be dynamically adjusted to account for patient condition.

Additionally, in certain embodiments, medical data obtained from a clinical network of physiological monitors can be stored or journaled in a journal database. The medical data can include device events that occurred in response to clinician interactions with one or more medical devices. The medical event data may also include device-initiated events, such as alarms and the like. The medical data stored in the journal database can be analyzed to derive statistics or metrics, which may be used to improve clinician and/or hospital performance.

As used herein the terms "round-robin database" and "RRDB," in addition to having their ordinary meaning, can also describe improved database structures having unique characteristics and features disclosed herein. Sometimes these structures are referred to herein as dynamic RRDBs or adaptive RRDBs.

FIG. **6** illustrates an embodiment of a clinical network environment **600**. The clinical network environment **600** includes a multi-patient monitoring system (MMS) **620** in communication with one or more patient monitors **640**, nurses' station systems **630**, and clinician devices **650** over a network **610**. In certain embodiments, the MMS **620** provides physiological data obtained from the patient monitors **640** to the nurses' station systems **630** and/or the clinician devices **650**. Additionally, in certain embodiments, the MMS **620** stores physiological information and medical event information for later analysis.

The network **610** of the clinical network environment **600** can be a LAN or WAN, wireless LAN ("WLAN"), or other type of network used in any hospital, nursing home, patient care center, or other clinical location. For ease of illustration, the remainder of this specification will describe clinical environments in the context of hospitals; however, it should be understood that the features described herein may also be employed in other clinical locations or settings. In some implementations, the network **610** can interconnect devices from multiple hospitals or clinical locations, which may be remote from one another, through the Internet, a leased line, or the like. Likewise, the various devices **620**, **630**, **640**, and **650** of the clinical network environment **100** may be geographically distributed (e.g., among multiple hospitals) or co-located (e.g., in a single hospital).

The patient monitors **640** may be point-of-care (POC) instruments or the like that monitor physiological signals detected by sensors coupled with medical patients. The patient monitors **640** may process the signals to determine any of a variety of physiological parameters. One example of a physiological parameter is blood oxygen saturation (SpO_2). Other examples of physiological parameters are described below with respect to FIG. **7**.

The patient monitors **640** can provide the physiological information to the MMS **620**. The patient monitors **640** can also provide information on medical events, such as alarms, to the MMS **620**. Alarms can be triggered, for example, in response to a physiological parameter falling outside of a normal range. Alarms can also include alerts regarding equipment failures, such as a probe-off condition where a sensor has fallen off of a patient. Other examples of medical events are described below with respect to FIG. **7**.

In various embodiments, the patient monitors **640** provide the physiological information and medical events to the MMS **620**. The MMS **620** is described in greater detail below. In some implementations, the patient monitors **640** may provide at least some of this information directly to the nurses' station systems **630** and clinician devices **650**.

The nurses' station systems **630** can be desktop computers, laptops, work stations, or the like that are located at a nurses' station. One or more nurses' station computers **630** can be located at a single nurses' station. The nurses' station computers **630** can receive and display physiological information and alarm data received from the MMS **620** (or monitors **640**). In certain embodiments, the nurses' station computers **630** use a graphical user interface (GUI) that provides a streamlined, at-a-glance view of physiological and medical information. An example of this GUI is described below with respect to FIG. **9**.

The clinician devices **650** can include any of a variety of devices used by clinicians, such as pagers, cell phones, smart phones, personal digital assistants (PDA), laptops, tablet PCs, personal computers, and the like. The clinician devices **650** are able to receive, in some embodiments, physiological information and alarms from the MMS **620** (or monitors **640**). Physiological and alarm data can be provided to a particular clinician device **650**, for example, in response to an alarm. The clinician devices **650** can, in some instances, receive values and waveforms of physiological parameters.

The MMS **620** in certain embodiments includes one or more physical computing devices, such as servers, having hardware and/or software for managing network traffic in the network **610**. This hardware and/or software may be logically and/or physically divided into different servers **620** for different functions, such as communications servers, web servers, database servers, application servers, file servers, proxy servers, and the like.

The MMS **620** can use standardized protocols (such as TCP/IP) or proprietary protocols to communicate with the patient monitors **640**, the nurses' station computers **630**, and the clinician devices **650**. In one embodiment, when a patient monitor **640** wishes to connect to the MMS **620**, the MMS **620** can authenticate the patient monitor **640** and provide the monitor **640** with context information of a patient coupled to the monitor **640**. Context information can include patient demography, patient alarm settings, and clinician assignments to the patient, among other things. Examples of context information are described herein. The MMS **620** may obtain this context information from the nurses' station systems **630** or other hospital computer systems, where patient admitting information is provided.

Upon connecting to a patient monitor **640**, the MMS **620** may receive physiological information and medical events from the patient monitors **640**. The MMS **620** may provide at least a portion of the physiological information and events to the nurses' station systems **630** and/or clinician devices **650**. For example, the MMS **620** may provide physiological data and alarms for a plurality of patient monitors **640** to a nurses' station system **630**, where nurses can evaluate the data and/or alarms to determine how to treat patients. Similarly, the MMS **620** may send wireless pages, emails, instant messages, or the like to clinician devices **650** to provide clinicians with physiological data and alarms.

Advantageously, in certain embodiments, the MMS **620** can store physiological information obtained from the patient monitors **640** in a round-robin database (RRDB) **624**. The RRDB **622** of various embodiments includes a streamlined database structure that facilitates rapidly storing and retrieving patient data. The RRDB **622** can therefore be used in certain embodiments to rapidly provide physiological trend data to the nurses' stations **630** and to the clinician devices **650**. Thus, for example, if a clinician desires to see a patient's physiological trends over a certain time period, such as the past hour, the clinician can use a nurses' station computer **630** or clinical device **650** to query the MMS **620**. The MMS **620** may then obtain physiological information corresponding to the desired time period from the RRDB **622**. Advantageously, the RRDB **622** can enable faster acquisition of trend data then is possible with relational databases currently used by hospital monitoring systems. Additional uses and optimizations of the RRDB **622** are described below.

In certain embodiments, the MMS **620** also archives or stores information about medical events in a journal database **624**. The medical events can include events recorded by devices such as the patient monitors **640**, nurses' station systems **630**, and clinician devices **650**. In particular, the medical events can include device events that occur in response to a clinician's interaction with a device, such as a clinician-initiated deactivation of an alarm. The medical events can also include device events that occur without a clinician's interaction with the device, such as the alarm itself. Additional examples of medical events are described below with respect to FIG. **7**.

The MMS **620** may analyze the medical event information stored in the journal database **624** to derive statistics about the medical events. For example, the MMS **620** can analyze alarm events and alarm deactivation events to determine clinician response times to alarms. Using these statistics, the MMS **620** may generate reports about clinician and and/or hospital performance. Advantageously, in certain embodiments, these statistics and reports may be used to improve the performance of clinicians and hospitals.

For instance, in certain situations, the reports might help hospitals discover the cause of issues with patient monitors **640**. The following example scenario can illustrate potential benefits of such a report. SpO_2 alarm levels tend to be different for adults and neonates. However, some clinicians may not know this and may modify neonate SpO_2 monitors to include adult alarm levels. These changes can result in many false alarms, which may cause clinicians to become frustrated and avoid using the patient monitors **640**. By journaling medical events such as clinician alarm changes, it can be determined by an analysis of the journaled data that clinicians were inappropriately adjusting alarm settings on neonate monitors. A hospital could then use this information to take corrective action, such as by fixing the alarm limits and training the clinicians.

Although not shown, administrative devices may be provided in the clinical network environment **600**. The administrative devices can include computing devices operated by hospital administrators, IT staff, or the like. Using the administrative devices, IT staff may, for example, promulgate changes to a plurality of patient monitors **640**, nurses' station systems **630**, and the MMS **620**. The administrative devices may also allow IT staff to interface third-party systems with the MMS **620**, such as electronic medical record (EMR) systems. The third party systems may be used, for instance, to change alarm settings on a plurality of monitors from an administrative device. Actions performed by administrators, IT staff, and administrative devices in general may also be journaled in the journal database **624**.

FIG. **7** illustrates a more detailed embodiment of a clinical network environment **700**. The clinical network environment **700** includes a network **710**, a patient monitor **740**, a nurses' station system **730**, an MMS **720**, an RRDB **722**, and a journal database **724**. These components may include all the functionality described above with respect to FIG. **6**. One monitor **740** and nurses' station system **730** are shown for ease of illustration. In addition, although not shown, the clinician devices **750** described above may also be included in the clinical network environment **700**.

The depicted embodiment of the patient monitor **740** includes a monitoring module **742**, an RRDB module **744**, and a journal module **746**. Each of these modules may include hardware and/or software. Other components, such as a communications module, are not shown but may be included in the patient monitor **740** in various implementations.

The monitoring module **742** can monitor physiological signals generated by one or more sensors coupled with a patient. The monitoring module **742** may process the signals to determine any of a variety of physiological parameters. For example, the monitoring module **742** can determine physiological parameters such as pulse rate, plethysmograph waveform data, perfusion index, and values of blood constituents in body tissue, including for example, arterial carbon monoxide saturation ("HbCO"), methemoglobin saturation ("HbMet"), total hemoglobin ("HbT" or "SpHb"), arterial oxygen saturation ("SpO_2"), fractional arterial oxygen saturation ("$SpaO_2$"), oxygen content ("CaO_2"), or the like.

In addition, the monitoring module **742** may obtain physiological information from acoustic sensors in order to determine respiratory rate, inspiratory time, expiratory time, inspiration-to-expiration ratio, inspiratory flow, expiratory flow, tidal volume, minute volume, apnea duration, breath sounds, rales, rhonchi, stridor, and changes in breath sounds such as decreased volume or change in airflow. In addition, in some cases the monitoring module **742** monitors other physiological sounds, such as heart rate (e.g., to help with probe-off detection), heart sounds (e.g., S1, S2, S3, S4, and murmurs), and changes in heart sounds such as normal to murmur or split heart sounds indicating fluid overload. Moreover, the monitoring module **742** may monitor a patient's electrical heart activity via electrocardiography (ECG) and numerous other physiological parameters.

In some implementations, the patient monitors **740** may also determine various measures of data confidence, such as the data confidence indicators described in U.S. Pat. No. 7,024,233 entitled "Pulse oximetry data confidence indicator," the disclosure of which is hereby incorporated by reference in its entirety. The patient monitors **740** may also determine a perfusion index, such as the perfusion index described in U.S. Pat. No. 7,292,883 entitled "Physiological

assessment system," the disclosure of which is hereby incorporated by reference in its entirety. Moreover, the patient monitors **740** may determine a plethysmograph variability index (PVI), such as the PVI described in U.S. Publication No. 2008/0188760 entitled "Plethysmograph variability processor," the disclosure of which is hereby incorporated by reference in its entirety. The parameters described herein are merely examples, and many other parameters may be used in certain embodiments.

In certain embodiments, the RRDB module **744** receives physiological information from the monitoring module **742** and transmits the physiological information over the network **710** to the MMS **720**. In response, the MMS **220** may store the physiological information in the RRDB **722**. Advantageously, in certain embodiments, the RRDB module **744** associates the physiological information with parameter descriptors prior to transmittal to the MMS **720**. The parameter descriptors may be identifiers that the RRDB module **744** associates with each measured physiological parameter value. The MMS **720** may use these parameter descriptors to identify the types of measured parameters received from the RRDB module **744**.

The parameter descriptors may be descriptors generated according to a markup language specification, such as an extensible markup language (XML) specification. As such, the parameter descriptors may include tags that enclose measured physiological values. These tags may be machine readable or human readable. For instance, the tags may include numerical identifiers (e.g., "0017") or descriptive identifiers, such as "SPO2" or "SPHB." A simplified example stream of physiological information from an SpO_2 sensor and an SpHb sensor associated with parameter descriptors might be as follows: <SPO2>96</SPO2> <SPHB>14.1</SPHB> <SPO2>97</SPO2> <SPHB>14.0</SPHB>, and so on.

In one embodiment, the RRDB module **744** may have stored (e.g., in a data file) a set of predefined parameter descriptors available for the patient monitor **740**. These parameter descriptors may correspond to possible parameters that may be measured by the patient monitor **740**. The parameter descriptors transmitted by the RRDB module **744** may depend on the particular subset of parameters measured by the patient monitor **740**.

If an additional (or different) parameter is subsequently measured by the patient monitor **740**, the RRDB module **740** may dynamically update the parameter descriptors that are sent to the MMS **720** Likewise, if the patient monitor **740** ceases to measure one of the parameters, the RRDB module **744** may cease to transmit the corresponding parameter descriptor to the MMS **720**.

The patient monitor **740** also includes a journal module **746** in the depicted embodiment. The journal module **740** may record medical events related to the patient monitor **740**. These medical events can include clinician-initiated events, such as changes to alarm settings (e.g., maximum and minimum permitted parameter values), types of parameters monitored/sensors connected to the patient monitor **740**, and the like. The journal module **746** may record these events by, for example, acting as a key logger or the like to record button presses of a clinician. The journal module **746** may also include current-sense circuitry to detect when sensors or cables are connected to the monitor **740**, and so forth. The medical events may also include non-clinician initiated events, such as alarms and alerts. The medical events can also include events from administrative devices (not shown), such as EMR updates to alarm settings across the network **710**.

The journal module **746** may log these events locally at the patient monitor **740**. In addition, or instead of logging the events locally, the journal module **746** may transmit information about the events to the MMS **720**. In turn, the MMS **720** can store the event information in the journal database **724**.

The nurses' station system **730** is shown in the depicted embodiment having a patient monitoring client **732**. The patient monitoring client **732** can enable the nurses' station system **730** to receive and display physiological information and alarm information. The patient monitoring client **732** includes a user interface module **734**. The user interface module **734** may include, for example, software for displaying physiological information, patient information, and medical event information for a plurality of patient monitors **740**. The user interface module **734** may also allow clinicians to admit and discharge patients, remotely modify device alarm limits, and the like. An example user interface that may be generated by the user interface module **734** is described below with respect to FIG. **9**.

The patient monitoring client **732** further includes a journal module **736**. The journal module **736** may include software for recording medical events related to the patient monitoring client **732**. For example, the journal module **736** may record which clinicians login to and logoff of the patient monitoring client **732** and when these events occur; admit and discharge events; and other clinician keystrokes, mouse clicks, and interactions with the patient monitoring client **732**. The journal module **736** may log this event information locally at the nurse's station system **730** and/or transmit the event information to the MMS **720**.

As shown, the MMS **720** may include a network management module **721**, an RRDB management module **723**, and a journal management module **725**, each of which may include one or more software components. In one embodiment, the network management module **721** receives messages containing physiological information and medical event data from the patient monitor **740**. The network management module **721** can provide at least a portion of this data to the nurses' station system **730** and clinician devices **650** of FIG. **6**. The network management module **721** can also provide the physiological information to the RRDB management module **723** and provide the medical event data to the journal management module **725**.

In certain embodiments, the RRDB management module **723** stores the physiological information received from the patient monitor **740** in the RRDB **722**. When the patient monitor **740** initially connects to the MMS **720**, or at another time, the RRDB management module **723** can create one or more RRDB files in the RRDB **722** corresponding to the patient monitor **740**. The contents of this file or files may depend on the type of patient monitor **740**, which may be defined by the patient monitor's **740** serial number, model number, vendor identifier, combinations of the same, or the like. Specific examples of the structure and contents of RRDB files are described in US Patent Publication 2009/0119330, the entire contents of which are hereby incorporated by reference herein.

The RRDB management module **723** can also provide physiological trend data stored in the RRDB to the network management module **721** for transmittal to monitors **740**, nurses' station systems **730**, and/or clinician devices. The RRDB management module **723** may also provide physiological data from the RRDB **722** to the journal management module **725** for purposes described below with respect to FIG. **8**B.

The journal management module **725**, in certain implementations, receives medical event data from the monitor **740** and the nurses' station system **730** and stores this data in the journal database **724**. In an embodiment, the journal database **724** is a relational database; however, other structures may be used. Each entry of event data may have a corresponding time stamp that indicates when an event occurred. This time stamp may be provided by the journal modules **746** or **736** or by the journal management module **725**. The journal management module **725** may also store event counters in the journal database **724** that reflect a number of times medical events occurred. For example, counters could be stored that count how many alarms occurred within a period of time or how many times a clinician logged on or logged off of a network device.

Advantageously, the journal management module **725** may, in certain embodiments, analyze the medical data in the journal database **724** to determine statistics or metrics of clinician and/or hospital performance. The journal management module **725** may provide an interface to users of the nurses' station system **730** or another computing device to access these statistics. In one example embodiment, journal management module **725** can analyze alarm events and alarm deactivation events to determine clinician response times to alarms. The journal management module **725** may further determine the clinician response times in nurses' day and night shifts. The journal management module **725** may generate reports of these statistics so that hospital administrators, for example, may determine which shifts perform better than others.

More generally, the journal management module **725** may generate reports about clinician and and/or hospital performance by analyzing various statistics derived from data in the journal database **724**. One example of a report is a monitoring report card, which grades a given hospital against other hospitals (or nurses' station against nurses' station, and the like) based at least partly on the derived statistics. Advantageously, hospital administrators, clinicians, and the like may use these statistics and reports to improve the clinician and hospital performance.

Some or all of the features of the clinical network environment **700** may be adapted in certain embodiments. For instance, either or both of the journal modules **746** or **736** may perform some or all of the functions of the journal management module **725**. Likewise, one or more journal databases **724** may be stored at the patient monitor **740** and/or nurses' work station **730**. Similarly, the RRDB module **724** may perform some or all of the functions of the RRDB management module **723**, and an RRDB **722** may be stored at the patient monitor **740**. In addition, in some implementations, the clinician devices **650** of FIG. **6** may have RRDB and/or journal modules as well. Many other adaptations, configurations, and combinations may be made in other embodiments. Additional information regarding embodiments of the RRDM can be found in US Patent Publication 2009/0119330.

FIG. **8**A illustrates an embodiment of a process **800**A for journaling medical events in a journal database. In one embodiment, the process **800**A may be implemented by any of the MMS's described above (e.g., the MMS **620** or **720**). In particular, the process **800**A may be implemented by the journal management module **725**. Alternatively, at least some of the blocks may be implemented by the journal modules **736**, **746**. Advantageously, in certain embodiments, the process **800**A facilitates the generation of reports based on the journaled data.

At block **802**, medical events are journaled in a journal database. In response to requests for report from a user (e.g., a clinician), at block **804** statistics about the medical events are obtained from the journal database. The statistics may include the type, frequency, and duration of medical events, the identity of clinicians or patients associated with the events, alarm response times, combinations of the same, and the like.

A report is generated at block **806** regarding the medical event statistics. At block **808**, the report is used to identify potential areas of improvement in hospital operations. For example, the report can be a "monitoring report card" that assigns scores to the hospital or clinicians of the hospital based on their performance.

FIG. **8**B illustrates an embodiment of a process **800**B for correlating data from a journal database and an RRDB. In one embodiment, the process **800**B may be implemented by any of the MMS's described above (e.g., the MMS **620** or **720**). In particular, the process **800**B may be implemented by the RRDB module **723** and journal management module **725**. Alternatively, at least some of the blocks may be implemented by the RRDB module **744** and journal modules **736**, **746**. Advantageously, in certain embodiments, the process **800**B enables physiological information from the RRDB and medical events to be correlated in time. Such a reconstruction of events and physiological data can be akin to aviation "black box" technology, allowing the user to replay clinical actions leading up to medical incidents.

At block **812**, the request is received from a user to review journaled and physiological data corresponding to a period of time. The user may be a clinician, hospital administrator, or the like, who wishes to determine the cause of a problem in the healthcare of a patient. For instance, the user may wish to determine why clinicians failed to respond when a patient's SpO_2 dropped below safe levels.

At block **814**, journaled data is retrieved for the specified period of time from a journal database. This block may be performed by the journal management module **725**. At block **816**, physiological data for the specified period of time is retrieved from an RRDB. This block may be performed by the RRDB management module **723**. The journal data is correlated with the physiological data with respect to time at block **818**. This correlation may include reconstructing a timeline of medical events, with values of physiological parameters (optionally including waveforms) provided in the correct time sequence on the timeline. In some embodiments, to facilitate this coordination between the RRDB management module **723** and the journal management module **725**, timestamps in each database **722**, **724** may be synchronized when the data is stored.

The correlated data is output for presentation to the user at block **820**. The output may include, for example, a graphical view of medical events superimposed on physiological information (e.g., a waveform), or the like. Many display formats may be used for the correlated data.

FIG. **9** illustrates an example graphical user interface (GUI) **900** for monitoring patients. The GUI **900** can be provided on a nurses' station system or the like. The GUI **900** can also be displayed on a clinician device.

The GUI **900** includes several display areas. In the depicted embodiment, the GUI **900** includes a patient status display area **910**. The patient status display area **910** shows the status of multiple patients in a hospital or other clinical location. In an embodiment, patient status display area **910** depicts patient status for patients in a hospital department.

Advantageously, in certain embodiments, the patient status display area **910** provides an "at-a-glance" view of multiple patients' health status.

The patient status display area **910** includes a plurality of patient status modules **912**. Each patient status module **912** can correspond to a patient monitor that can be coupled to a medical patient. Each patient status module **912** can display a graphical status indicator **914**. An example graphical status indicator **914** is shown in the screens **900** as a miniature patient monitor icon. The graphical status indicator **914** can selectively indicate one of several states of a patient monitor. In one embodiment, four possible patient monitor states can be depicted by the graphical status indicator **914**. These include an alarm condition, a no alarm condition, patient context information status, and connection status.

In various implementations, the graphical status indicator **914** changes color, shape, or the like to indicate one of the different patient monitor states. For example, if an alarm condition is present, the graphical status indicator **914** could turn red to signify the alarm. If there is no context information available for the patient (see FIG. **1**), then the graphical status indicator **914** could turn yellow. If the device is not connected to the patient or the network, then the graphical status indicator **914** could turn gray. And if there is no alarm condition, if there is context information, and if the patient monitor is connected to the patient and the network, then the graphical status indicator **914** could turn green. Many other colors, symbols, and/or shapes could be used in place of or in combination with the above-described embodiments.

Advantageously, the graphical status indicator **914** shows at a glance the status of a patient monitor. Thus, in the patient status display area **910**, several graphical status indicators **914** corresponding to several patients show an at-a-glance view for the patient monitors corresponding to these patients. A clinician can therefore readily see the needs that a patient might have with regards to alarms, connection status, and context information.

Currently available graphical user interfaces for nurses' station computers tend to show a plurality of wave forms or changing physiological parameter numbers for each patient. This method of displaying patient information can be cluttered, confusing, and even hypnotic in some situations. Nurses working on a night shift, for instance, may find it difficult to concentrate on an alarm when several other patients' indicators on the display have changing numbers, changing waveforms, or the like. In contrast, in the graphical interface herein described, when the graphical status indicator **914** indicates an alarm condition, this alarm condition can stand out and be immediately recognized by the clinician.

Moreover, the graphical status indicator **914** simplifies the first level of analysis that nurses tend to perform. In currently available devices, nurses often have to analyze waveforms at the nurses' station to determine the health status of a patient. However, using the screens **900**, a nurse need not interpret any waveforms or changing parameters of the patient, but instead can rely on the graphical status indicator **914** that indicates the presence of an alarm.

In certain embodiments, the patient status modules **912** can be selected by a single mouse click or the like. Selecting a patient status module **912** in one embodiment can bring up a patient monitor view area **920**. The patient monitor view area **920** shows a view of a patient monitor corresponding to a selected patient status module **912**. In certain implementations, the patient monitor view area **920** can show a view of the screen from the actual patient monitor device at the bedside of the patient. Thus, a clinician can readily recognize the physiological parameters of the patient in a format that the clinician is likely familiar with. The patient monitor view area **920** is currently receiving physiological information from a patient.

A history view area **930** in certain implementations can show medical event data corresponding to a selected patient monitor status module **912**. This medical event data can be obtained from a journal database for inclusion in the GUI **900**. The historical view **930** can show, for example, when a sensor was connected or disconnected from a patient, when alarms were active, and when a patient was admitted to the hospital or department. Although not shown, the history view area **930** can also be configured to show trend data obtained from an RRDB instead of, or in addition to, the journaled data.

Transmission of Patient Information to Remote Devices

In some embodiments, the patient monitoring devices described herein are capable of transmitting patient information to one or more remote devices for review by a clinician. For example, such remote devices can include remote computers, smart phones, PDAs, etc. This is useful because it enhances the ability of a clinician to monitor a patient's condition remotely. For example, the clinician need not be at the patient's bedside or even at a hospital or other patient care facility in order to effectively monitor the patient's condition.

In some embodiments, any of the information collected by a patient monitoring device (e.g., the patient monitoring devices described herein) can be transmitted to a remote device. Such information can include, for example, values, trend data, etc. for a medical parameter (e.g., blood oxygen saturation, pulse rate, respiration rate, etc.). It can also include video of the patient and/or audio from the patient and/or the patient's room. For example, video cameras and/or microphones can be provided in the patient's room. In some embodiments, a video camera and/or microphone is incorporated with, for example, a medical monitoring device, such as those described herein. The video camera can image the patient using visible light when the ambient light in the patient's room is of sufficient intensity. The video camera can also be capable of detecting, for example, infrared light when the patient's room is too dark to provide video of acceptable quality using visible light. The video camera can also include an infrared illumination source to illuminate the patient and/or his or her surroundings. In some embodiments, the video camera includes an ambient light sensor that can be used to automatically switch the video camera into infrared mode when the ambient light falls below some threshold. The light sensor can also be used for switching on an infrared illumination source if one is included.

The transmission of patient information (e.g., medical parameter data, video/audio of the patient, etc.) can be made using, for example, one or more communication networks (e.g., computer networks such as LANs, WLANs, the Internet, etc., telephone networks, etc.). In some embodiments, one or more communication networks that are entirely or partially physically located in a hospital or other patient care center can be used. In some embodiments, external communication networks can be used to reach remote devices throughout the world. Thus, clinicians can remotely obtain a vast amount of information regarding the condition of their patients regardless of the clinician's location. In some embodiments, the clinician may also have the capability to directly communicate with the patient. For example, a

patient monitoring device could include a speaker for broadcasting audio from the clinician's remote device to the patient. Similarly, a patient monitoring device could include a display for showing video from the clinician's remote device (e.g., video teleconferencing). In this way, the exchange of information can be bidirectional to allow the clinician to directly interact with the patient.

Hospital Systems with Location Awareness of Devices and Clinicians

Advanced monitoring systems are capable of displaying many different physiological parameters in many different formats. One possible drawback to this substantial performance capability and display flexibility is that excessive information may be presented to the caregivers that use these systems. These caregivers may include physicians, respiratory therapists, registered nurses, and other clinicians whose uses of the monitoring systems may vary from the taking of routine vital signs to the diagnosis and treatment of complex physiological conditions to clinical research and data collection.

Patient monitoring devices, such as those described herein, may include a keyboard, touchscreen, or other input device to allow a clinician to interact with the device. Such user interface devices can be used to allow a clinician to input login information, such as, for example a username and password. In some cases, a monitoring device may require a clinician to login to the device, for example, before permitting access to one or more of the functions offered by the device, and/or before permitting access to certain information available at the device. The nurses' station, or central monitoring station, as described herein, is an example of one such monitoring device that may require a clinician to login in order to use it. Bedside patient monitors may require a clinician to login before initializing monitoring of a new patient. Even where a clinician is not required to login to a patient monitoring device before using it, the device may still require some type of interaction with an input device in order to cause it to take a particular action from amongst a set of available actions offered by the patient monitoring device.

For example, user input may be required in order to configure a patient monitoring device in a desired manner. In some embodiments, a clinician may use an input device to change the content offered on the display of the patient monitor device, or the formatting of the content, to suit his or her preferences. In some instances, a nurse may use the input device to manually configure the central monitoring station to display only monitoring information for those patients that are assigned to that particular nurse rather than displaying, for example, all the patients on the entire floor. A clinician may also use an input device to alter patient monitoring settings such as, for example, options for calculating physiological parameter values from raw data, alarm types, physiological parameter alarm limits (e.g., alarm thresholds), etc.

Given the time demands placed on clinicians in busy hospitals, this process of manually interacting with a patient monitoring device by, for example, physically manipulating an input device can be burdensome, especially when it may need to be repeated over and over throughout the day. In some cases, the time required to manually interact with a patient monitor device in order to access a particular function or configure the device can even jeopardize a patient's well-being in particularly urgent circumstances. For at least the foregoing reasons, it would be advantageous for hospital equipment, such as bedside patient monitors, central monitoring stations, and other devices, to have the capability to automatically detect the presence of a clinician, and to, for example, take some predetermined action based on the identity of the clinician whose presence is detected.

In some embodiments, a proximity display monitor advantageously adapts an advanced monitoring system to various user needs and preferences by adapting the display to the current observer according to, for example, preference, priority, or user acknowledgement. Accordingly, displayed parameters and formats may be chosen by default according to a predefined user class or customized for particular individuals or groups of individuals. One method of identifying persons in the vicinity of a proximity display is by an ID tag or other token. The ID tag may communicate the user to the proximity display monitor via radio-frequency identification (RFID) or wireless radio transmission as examples. If multiple users are in range of a proximity display monitor, a priority scheme or a user acknowledgment may be used to determine which users are accommodated.

In some embodiments, a proximity display monitor has a monitor and an interconnected sensor, the sensor transmits optical radiation into a tissue site and generates a sensor signal responsive to the optical radiation after attenuation by pulsatile blood flow within the tissue site. The monitor may compute physiological parameters responsive to the sensor signal and utilize a proximity display to show the physiological parameters on screen according to a display preference associated with a user in proximity to the monitor. A display can be incorporated with the monitor so as to present the physiological parameters for viewing by a caregiver. A transceiver can be incorporated with the monitor and may be responsive to an identification signal. The identification signal can correspond to a caregiver. A transmitter carried by the caregiver can send the identification signal over a range, for example, approximating the distance from the monitor that a person can reasonably view the display. A preferred screen can present the physiological parameters on the display according to the display preference associated with the caregiver as indicated by the identification signal.

In some embodiments, a proximity display monitor comprises a monitor having a display and a wireless transceiver. The wireless transceiver can be responsive to identification signals which indicate the proximity to the monitor of any users, who have corresponding display preferences. Preferred screens may present the physiological parameters on the display according to the display preferences.

In some embodiments, a proximity display monitor has an optical sensor attached to a fleshy tissue site. A sensor signal may be responsive to optical radiation transmitted by the sensor and detected by the sensor after absorption by pulsatile blood flow within the tissue site. The sensor signal can be communicated to a monitor, which processes the sensor signal so as to derive physiological parameters responsive to constituents of the pulsatile blood flow. The identity of a user in proximity to the monitor can be wirelessly signaled to the monitor. A screen preference, for example, can be determined from the user identity and used to display the physiological parameters on a monitor display.

In some embodiments, a proximity display monitor comprises a processor and a display. The processor can be responsive to a sensor signal generated from optical radiation transmitted into a fleshy tissue site and detected after attenuation by pulsatile blood flow within the tissue site. The processor can be configured to calculate a plurality of physiological parameters indicative of constituents of the pulsatile blood flow. The display may provide a visual representation of the physiological parameters values for

viewing by proximate users. A wireless communications means can determine the identities of proximate users. Screen preference means may present the physiological parameters on the display. A lookup table means can relate the user identities to the screen preferences.

FIG. **10** illustrates a physiological measurement system having a noninvasive sensor **1010** attached to a tissue site **1000**, a patient monitor **1020**, and an interface cable **1030** interconnecting the monitor **1020** and the sensor **1010**. The physiological monitoring system may incorporate pulse oximetry in addition to advanced features, such as a multiple wavelength sensor and advanced processes for determining physiological parameters other than or in addition to those of pulse oximetry, such as carboxyhemoglobin, methemoglobin and total hemoglobin, as a few examples. The patient monitor **1020** has a proximity display **1021** that presents measurements of selected physiological parameters and that also provides visual and audible alarm mechanisms that alert a caregiver when these parameters are outside of predetermined limits. The patient monitor **1020** also has keys **1022** for controlling display and alarms functions, among other items. The proximity display **1021** and keys **1022** provide a user interface that organizes many parameters so that a caregiver can readily ascertain patient status using, for example, a portable, handheld device.

FIG. **11** illustrates various screens **1150** for a proximity display **1021** (FIG. **10**) advantageously configured to respond to the presence of a particular user **1130** and to that user's display preference. Users may be any of various caregivers such as treating physicians or attending nurses. In an embodiment, the proximity display **1021** (FIG. **10**) may also respond to any of a particular group of users.

As described with respect to FIG. **13**, below, the presence or proximity of a particular user or group of users to the monitor **1020** (FIG. **10**) may be determined by a user wearing an RFID (radio frequency identification) tag or other wireless communications. Then, a particular screen or screens can be presented on the display according to a predetermined display preference associated with the user. In this manner, a proximity display **1021** (FIG. **10**) is tailored to the preferences of monitor users. An "RFID tag" or simply "tag" can include any wireless communication device that can remotely identify a proximate user to a monitor. Tags include, but are not limited to, devices in the form of badges, tags, clip-ons, bracelets or pens that house an RFID chip or other wireless communication components. Tags also encompass smart phones, PDAs, pocket PCs and other mobile computing devices having wireless communications capability.

As shown in FIG. **11**, by example, an anesthesiologist **1131** proximate the monitor is identified and the display is changed to a screen **1110** showing pulse rate trend. When a nurse **1132** is proximate the monitor, the display is changed to a screen **1120** showing pulse oximetry parameters, a plethysmograph and alarm limits. When a respiratory therapist **1133** is proximate the monitor, the display is changed to a screen **1140** showing pulse oximetry, abnormal hemoglobin and perfusion indices.

In some embodiments, a proximity display monitor responds to the departure of all proximate users by automatically dimming the display to a reduced brightness setting. This feature advantageously avoids disturbance of a patient who is sleeping or attempting to sleep. In some embodiments, a proximity display monitor responds in a similar manner by automatically silencing pulse "beeps" and other non-critical sounds when there are no proximate users.

FIG. **12** illustrates a proximity display monitor **1200** that responds to a nearby user **1280** so as to display calculated parameters according to a user display preference. As shown in FIG. **12**, the proximity display monitor **1200**, in some embodiments, has a front-end **1210** that interfaces with an optical sensor (not shown). The optical sensor generates a sensor signal responsive to pulsatile blood flow with a patient tissue site. An optical sensor is described in U.S. patent application Ser. No. 11/367,013 titled Multiple Wavelength Sensor Emitters, cited above. The front-end **1210** conditions and digitizes the sensor signal **1212**, which is input to a digital signal processor (DSP) **1220**. The DSP **1220** derives physiological parameters **1222** according to the sensor signal **1212**. The calculated parameter values are communicated to a display driver **1230**, which presents the parameters on the display **1270** according to a predetermined format. A monitor having a front-end and DSP is described in U.S. patent application Ser. No. 11/366,208 titled Noninvasive Multi-Parameter Patient Monitor, cited above.

Also shown in FIG. **12**, the proximity display monitor **1200** has a transceiver or receiver **1240**, a lookup table **1250** and display preferences **1258**. The user **1280** has an ID tag **1260** that identifies the user **1280** to the transceiver **1240**. When the user **1280** is in the vicinity of the proximity display monitor **1200**, the ID tag **1260** is able to communicate with the transceiver **1240** so as to identify the user **1280**. In an embodiment, the transceiver **1240** is an RFID reader and the ID tag **1260** has an embedded RFID chip containing a user code **1252**. In another embodiment, the transceiver **1240** complies with one or more short-range wireless communications standards, such as Bluetooth®. The user **1280** can initiate communications with the proximity display monitor **1200** by, for example, pressing a button or similar initiator on the ID tag **1260**, and a user code **1252** is transmitted to the transceiver **1240**. The transceiver **1240** communicates the user code **1252** to the DSP **1220**. The DSP can access the lookup table **1250** so as to derive a display preference **1258** from the received user code **1252**. The display preference **1258** indicates the display parameters **1222** and screen format **1224**, which are communicated to the display driver **1230**.

Further shown in FIG. **12**, in some embodiments, the lookup table **1250** relates the user code **1252** to a caregiver ID **1256** and a priority **1254**. When multiple users are in the vicinity of the proximity display monitor **1200**, the priority **1254** determines which display preference **1258** is used to configure the display **1270**.

FIG. **13** illustrates a display preference screen **1300**, which provides information for a particular row of the look-up table **1250** (FIG. **12**). A setup or registration procedure allows users to specify one or more profiles including, for example, a display preference and various options for calculating parameters and triggering alarms.

FIG. **14** is a schematic diagram of a patient monitoring device **1400** that is capable of automatically detecting the presence of a clinician token **1410**. In some embodiments, the clinician token **1410** is a portable item meant to be, for example, worn or carried by a clinician throughout the day. The patient monitoring device **1400** is able to recognize the presence of the clinician based upon the presence of that clinician's token.

The patient monitoring device **1400** includes a detector such as, for example, a communication module **1402**. The patient monitoring device **1400** also includes a display **1404**, and a processor **1406**. The processor **1406** can be used, for example, for carrying out clinically-useful tasks on the basis

of physiological information collected from one or more patients (e.g., calculating physiological parameter values, determining alarm conditions, outputting physiological information via a clinician user interface, notifying a clinician of an alarm condition, etc.) The patient monitoring device **1400** can also include other modules to assist in the monitoring of patients, as described herein (e.g., an interface for receiving physiological information from a medical sensor or computer network, a user interface for facilitating interaction with a clinician, etc.). In some embodiments, the communication module **1402** is a transmitter, a receiver, or a transceiver. Other types of communication modules can also be used. In some embodiments, the communication module **1402** is a short-range transceiver. The short range transceiver can be, for example, a Bluetooth-enabled transceiver. Bluetooth is a wireless protocol for exchanging data between devices over relatively short distances. The communication module **1402** can also be an infrared transceiver, an RFID tag, or any other means of communication (e.g., short-range communication).

The communication module **1402** is capable, in some embodiments, of detecting signals from a remote device within a detection area **1420**. The size of the detection area of **1420** can be determined by, for example, the power levels of communication signals from the communication module **1402**. The size of the detection area **1420** may also be affected by the surroundings of the patient monitoring device **1400**. In some embodiments, the detection area **1420** is configured to have a radius of 30 feet or less. In some embodiments, the radius of the detection area **1420** is 20 feet or less. In some embodiments, the radius is 10 feet or less, while in some embodiments, the radius is 5 feet or less, or 3 feet or less.

The clinician token **1410** can likewise include a communication module **1412**, which can be, for example, a transmitter, a receiver, or a transceiver, though other types of communication modules may also be used. As is the case with the patient monitoring device **1400**, the communication module **1412** included with the clinician token **1410** may be a short range transceiver, such as, for example, a Bluetooth transceiver. The patient monitoring device **1400** is capable of detecting the presence of a clinician based on, for example, recognition of one or more communication signals from a clinician token **1410**. A communication signal from the clinician token **1410** may come, for example, in response to a communication initiated by the patient monitoring device **1400**, or the communication signal from the clinician token **1410** may be initiated by the clinician token itself. Many different methods can be used for initiating, for example, wireless communication between remote devices.

The clinician token **1410** may also carry information, for example, in a memory. The memory may be, for example, volatile or nonvolatile memory. The information may be hardwired into the clinician token **1410** or programmable. In some embodiments, the clinician token **1410** includes a clinician ID **1414** that is unique to the clinician to whom the clinician token **1410** is assigned. The clinician token **1410** may also include other information such as, for example, a clinician's login information (e.g., user name and password), a code or other indicator for initiating a predetermined action to be performed by the patient monitoring device **1400** upon recognition of the clinician's presence (logging in the clinician, setting configuration preferences of the patient monitoring device **1400**, enabling a function, etc.).

The clinician token **1410** may also include an input module **1416** that allows the clinician to cause the communication module **1412** to remotely communicate with, for example, the patient monitoring device **1400**, or some other device that forms a part of the hospital's patient monitoring network. For example, the input module **1416** may include one or more buttons, or other input devices, that allow the clinician to initiate a communication with the patient monitoring device **1400** for the purpose of having that device recognize the clinician's presence. In addition, the clinician may use the input module **1416** to, for example, call in an emergency response team if the clinician discovers that a particular patient is in need of emergency attention, or to silence a monitoring alarm. The input module **1416** can also be used for other purposes, depending upon the application.

In some embodiments, the clinician token **1410** is a cell phone, notebook computer, PDA device, headset, etc., any one of which may be, for example, Bluetooth-enabled. In some embodiments, the clinician token **1410** is the pager, or other notification device, used to notify clinicians of physiological parameter alarm conditions, as described herein. In some embodiments, the clinician token **1410** is an active or passive RFID tag. An active RFID tag may be WiFi-enabled, for example. In some embodiments, the clinician token **1410** is a barcode (e.g., two-dimensional or three-dimensional). In some embodiments, the clinician token **1410** is a part of the clinician's body. For example, the clinician token **1410** may be a fingerprint, a retina, the clinician's face, etc. In such embodiments, the clinician ID **1414** is actually a unique biometric signature of the clinician. The communication module **1402** may be selected based upon the type of clinician token **1410** with which it is to communicate. For example, the communication module **1402** in the patient monitoring device **1400** may be an RFID interrogator, a barcode scanner, a fingerprint scanner, a retina scanner, a facial recognition device, etc.

In some embodiments, the clinician token **1410** is advantageously a consumer device that can be registered with the patient monitoring device **1400** but that has no prior connection or relationship with, for example, the patient monitoring device **1400**, a patient monitoring system, the hospital, etc. For example, the clinician token **1410** can be a consumer device that is not designed specifically for the purpose of communicating with the patient monitoring device **1400**, or any other device configured to be able to detect the presence of the clinician token. Many clinicians will already own, for example, a cell phone which is carried on the clinician's person throughout the day for the clinician's personal use. In some embodiments, the clinician's personal electronic device can function as the clinician token **1414**, for example, after a registration process that will be described herein. This can be advantageous because it does not require investment on the part of the hospital or other caregiver facility to provide each clinician with a special-purpose clinician token **1410**. Nevertheless, in some embodiments, the clinician token **1410** is a special-purpose device provided to the clinician for the primary purpose of operating with, for example, patient monitoring devices (e.g., **1400**) having presence detection functionality.

In some embodiments, the clinician token **1410** is capable of responding to, for example, interrogation from a patient monitoring device only with a fixed response signal (e.g., a clinician ID **1414**). In some embodiments, however, the clinician token **1410** is capable of transmitting multiple, and/or variable, signals and information to the patient monitoring device **1400**. The clinician token **1410** may include a processor capable of executing, for example, software applications that allow the clinician token **1410** the capability of a variety of intelligent communications with the patient monitoring device **1400**.

In some embodiments, a registration process is completed before the clinician token **1410** is used with the patient monitoring device **1400** to implement presence detection functionality. For example, during a registration process, the clinician token **1410** may be endowed with a unique clinician ID **1414** assigned to a particular clinician. This clinician ID may be stored in a database that is, for example, accessible by the patient monitoring device **1400** such that the patient monitoring device **1400** can determine the identity of the clinician based upon the clinician ID **1414** stored in the clinician token **1410**. The clinician ID **1414** can also be associated in the database with, for example, the clinician's assigned login information for accessing the patient monitoring device **1400**.

The database can also store an indication of the action, or actions, that the clinician desires a particular patient monitoring device to take upon detection of the clinician's presence. The database can store the clinician's configuration preferences for the patient monitoring device. For example, the particular physiological parameters and other monitoring information that are shown on the display **1404** of the patient monitoring device **1400** may be configurable. In the case of bedside patient monitors, for example, the display **1404** may be capable of showing numerical indicators of a particular physiological parameter, graphical indicators of the physiological parameter, visual alarms, multiple physiological parameters simultaneously, signal quality of physiological parameter signals from a patient sensor, etc. The clinician's configuration preferences can indicate to the monitoring device **1400** what type of information to display and how to format the displayed information. The clinician's configuration preferences for the patient monitoring device **1400** can also include patient monitoring settings such as, for example, physiological parameter alarm limits.

In the case of, for example, a central monitoring station, such as the type described herein, the clinician's configuration preferences may likewise include the type and display format of a physiological parameter, or other monitoring information, that is shown for each of the patients being monitored at the central monitoring station. In addition, the clinician's configuration preferences can include a fixed or dynamic list of patient rooms, or patient names, to be displayed at the central monitoring station. These rooms, or patients, can be those currently assigned to that particular clinician, for example. In general, however, the clinician's configuration preferences that are associated with the clinician ID **1414** can include any configurable feature, aspect, or function of the patient monitoring device **1400**.

The database can associate with the clinician ID **1414** a particular action that the clinician may wish to initiate upon entering the detection area **1420** of the patient monitoring device **1400**. Examples of such actions that can be initiated automatically upon detection of the clinician's presence are described herein. In addition, in some embodiments, the database can also associate with the clinician ID **1414** a priority level. The priority level can indicate which clinician should be given priority access to a medical monitoring device **1400**, for example, when multiple clinicians are detected in the detection area **1420** simultaneously.

In some embodiments, the clinician's assigned login information, monitoring device configuration preferences, list of actions to automatically initiate upon recognition of the clinician's presence, priority level, and/or other information can be stored by the clinician token **1410** itself. In such embodiments, this information may be transmitted directly to the patient monitoring device **1400** by the clinician token **1410** as opposed to the patient monitoring device

1400 obtaining the information from a database using the clinician ID **1414** stored on the token **1410**. Other methods can also be used in order to associate, for example, a clinician ID **1414** with a predetermined action (e.g., logging in, configuration change, etc.) that the clinician wishes the patient monitoring device **1400** to take or assume when the clinician is in the detection area **1420** of the device **1400**.

In some embodiments, once a registration process is complete, the patient monitoring device **1400** is capable of detecting the presence of a particular clinician based upon the clinician's token **1410**, and of taking, for example, a clinician-specific action based upon recognition of the clinician's presence. In some embodiments, the processor **1406** of the patient monitoring device **1400** is configured to execute detection logic **1408** for determining when a clinician token **1410** is or is not present in the detection area **1420** of the monitoring device **1400**. In some embodiments, the detection logic **1408** is a set of rules or other criteria that must be satisfied before a clinician token **1410** is determined to be present in the detection region **1420**, or before some clinician-specific action is performed.

FIG. **15** is a flowchart illustrating detection method **1500** for detecting the presence of a clinician token (e.g., **1410**) within the detection region of a patient monitoring device. The detection method **1500** can begin, for example, at a waiting state **1502** where the patient monitoring device **1400** has not detected the presence of a clinician. In the waiting state **1502**, the patient monitoring device **1400** can allow manual access, for example, to the features and information that can be provided by the device **1400**. In the waiting state **1502**, the patient monitoring device can also allow manual configuration of the device, or interaction with the device, by a clinician using an input device such as a keyboard, mouse, or touchscreen. Thus, the waiting state **1502** advantageously allows clinicians who may not have an assigned clinician token **1410** to nevertheless use and interact with the patient monitoring device **1400**.

At decision block **1504**, the processor **1406** executes the detection logic **1408** to determine whether a signal is detected from a clinician token **1410**. For example, in some embodiments, the communication module **1402** of the patient monitoring device **1400** may, for example, continuously, or periodically, transmit a clinician token discovery signal. At decision block **1504**, the processor **1406** can determine whether a response has been received from a clinician token **1410** to the patient monitoring device's discovery signal. Alternatively, or additionally, the clinician token **1410** can be configured to, for example, continuously, or periodically, transmit a discovery signal which the patient monitoring device **1400** can detect. Response signals from the clinician token **1410** can include, for example, the clinician ID **1414** or other information. If no signal is detected from a clinician token **1410**, then the detection method **1500** returns to the waiting state **1502**. If, however, a signal from a clinician token **1410** is detected, then the detection method **1500** can proceed to the next decision block **1506**.

At decision block **1506**, the processor **1406** executes the detection logic **1408** to determine whether the detected signal from the clinician token **1410** exceeds a signal strength threshold value. This test can be useful, for example, as an estimate of the physical distance between the clinician token **1410** and the patient monitoring device **1400**. For example, the patient monitoring device **1400** may be configured such that whether or not a detection event occurs, and/or the particular predetermined action it takes upon detection of a clinician, is dependent upon the estimate of

the physical distance between the clinician and the patient monitoring device **1400**. This may be useful, for example, in the case of a central monitoring station that is near a high traffic area where many clinicians regularly pass by. In such situations it may be advantageous to set the signal strength threshold used in decision block **1506** at a relatively high level so as to limit the clinician detection events to situations where a clinician is a relatively small distance away from the central monitoring station. Thus, the signal strength threshold can be configurable based, for example, upon a desired physical distance from a clinician token **1410** before recognizing a clinician presence detection event. If the signal strength of the signal detected from a clinician token **1410** is below the signal strength threshold used by the decision block **1506**, then the detection method **1500** returns to the waiting state **1502**. If, however, the signal strength exceeds the threshold, then the detection method **1500** can proceed to the next decision block **1508**.

At decision block **1508**, the processor **1406** executes the detection logic **1408** to determine whether the signal strength of the signal from the clinician token **1410** has exceeded the signal strength threshold for a proximity time that is greater than a time threshold. This test can be useful to avoid recognizing a clinician presence detection event in cases where a clinician passes nearby the patient monitoring device **1400** but does so only transiently, not remaining within the detection region **1420** for a long enough period of time to merit a clinician presence detection event. This test can likewise help eliminate false clinician presence detection events in high-traffic areas around a patient monitoring device **1400** where many different clinicians routinely and regularly pass by. The proximity time threshold used by the decision block **1508** can be configurable. In some embodiments, the proximity time threshold may be set at, for example, 1 second, 2 seconds, or 5 seconds. Other proximity times can also be used, however. If the proximity time for a detected clinician token **1410** does not exceed the proximity time threshold used by decision block **1508**, then the detection method **1500** returns to, for example, the waiting state **1502**. If, however, the proximity time of the clinician token **1410** exceeds the proximity time threshold, then the detection method **1500** can proceed to block **1510**.

At block **1510**, a clinician presence detection event is recognized. At such time, the patient monitoring device **1400** can enable or initiate, for example, some predetermined action based upon the clinician identity associated with the recognized clinician token **1410**. For example, the patient monitoring device **1400** can login the clinician, change a configuration setting, authorize some action or feature that is typically restricted absent the presence of a clinician, etc. In the detection method **1500** illustrated in FIG. **15**, whether or not a clinician presence detection event occurs is dependent upon the signal strength of a signal from the clinician token **1410** as well as the length of time that the signal from the clinician token **1410** exceeds a signal strength threshold. In some embodiments, however, a clinician presence detection event can be recognized based only on signal strength from the clinician token **1410**, or based only on the length of time that a signal is detected from a clinician token **1410**.

In some embodiments, other factors can be included in the detection logic **1408**, whether alone or in combination with signal strength from the clinician token **1410** and proximity time. For example, the recognition of a clinician presence detection event can be based, at least in part, on the identity of the clinician (some patient monitoring devices **1400** may only be accessible to certain clinicians). In addition, the recognition of a clinician presence detection event can be based upon the assigned priority of the clinician. For example, a nurse supervisor could be assigned a higher priority than other nurses on the shift such that the presence of the nurse supervisor will be recognized by a patient monitoring device **1400** even when the presence of another nurse has already been recognized by the device. The converse situation, however, may not result in a new clinician presence detection event; the detection of a lower priority clinician may not result in a detection event if the presence of a higher priority clinician has already been recognized by the patient monitoring device **1400**. The priority level is one example of a tiebreaker criteria that can be used by the detection logic **1408** in the event that multiple clinician tokens meet the other requirements to initiate a clinician detection event at the same time. Other criteria can also be used in this tiebreaker role.

It should be appreciated that a wide variety of factors can be included in the detection logic **1408** depending upon the hospital, the type of medical equipment involved (e.g., patient monitoring equipment or some other type of medical device). In addition, such factors can be accounted for in the detection logic **1408** in a variety of ways. For example, the detection logic **1408** can determine when thresholds are exceeded, when a Boolean expression is true or false, when a fuzzy logic expression is true or false, when a mathematical equation is satisfied or not, when a compound rule is satisfied or not, etc.

When a clinician detection event has been realized according to, for example, the detection method **1500**, the patient monitoring device **1400** can respond in a number of different ways. For example, the patient monitoring device **1400** can initiate a predetermined action based upon the identity of the clinician whose token has been detected in proximity to the monitoring device. In some embodiments, the predetermined action is that the patient monitoring device **1400** automatically logs the clinician in without requiring the clinician to, for example, physically interact with an input device. This process saves the clinician time and, in some cases, can also save patient lives. As described herein, the clinician's login information can be transmitted to the patient monitoring device **1400** from the clinician token **1410**, or it can be retrieved from a database using the clinician ID **1414** from the token **1410**.

In some embodiments, the patient monitoring device enables or disables a particular feature based upon detection of the clinician token **1410**. For example, the patient monitoring device may enable/disable menus and buttons (e.g., alarm limit menu, alarm silence, all mute, etc.) based upon the credentials of the detected clinician. In some embodiments, the patient monitoring device **1400** begins transmission of patient monitoring information to a remote device upon detecting the presence of a clinician. For example, a bedside patient monitor capable of capturing breathing sounds from a patient could automatically begin transmission of those breathing sounds to the clinician's Bluetooth headset, which, incidentally, can serve as the clinician token **1410** as well. In other embodiments, the patient monitoring device **1400** could begin transmission of any type of monitoring information to a remote device via, for example, the Internet upon detecting the presence of a particular clinician. For example, the patient monitoring device **1400** can transmit the patient's oxygen saturation trend data to the clinician's computer for later analysis and diagnosis. The patient monitoring device **1400** can also transmit any other type of patient information (e.g., medical parameter values and/or trend data, video and/or audio from the patient's room, etc.)

to, for example, the clinician's computer, or some other device, in response to detection of the presence of some particular clinician in proximity to the patient monitoring device **1400**.

In some embodiments, the patient monitoring device automatically updates its configuration based upon configuration preferences of a detected clinician. For example, the patient monitoring device **1400** could alter the content of the information it displays or the format of the information that it displays. These configuration changes can be made based upon settings that the clinician indicates during the registration process for the clinician token **1410**. An example of such an embodiment is illustrated in FIG. **16**. In some embodiments, a patient monitoring device changes the layout of a display screen (e.g., the number of parameters shown, the waveforms shown, trends, and other screen controls). Display layouts can be selected from predefined layouts, or a clinician can make a custom layout. The same is true of other configuration settings. Configuration settings can be associated with clinicians at an individual user or group level. A hierarchy of layouts modes can be established for layout conflicts.

The patient monitoring device **1400** can also update other configuration settings based upon registered preferences of the clinician. These can include physiological parameter alarm limits, alarm silence, all mute, averaging time, algorithm mode, etc., for example. In addition, the patient monitoring device **1400** could automatically create some type of report, such as a report of all alarm conditions that have been registered by that monitor over a predetermined period of time.

In addition, alarm annunciation and behavior can be altered in response to a clinician proximity detection event. For example, if the clinician is approaching a bedside patient monitoring device **1400** that is currently registering an alarm condition, the alarm can automatically be silenced in recognition that the clinician has entered within a certain radius of the monitoring device **1400**. In some embodiments, the way that the patient monitoring device **1400** notifies of an alarm condition can be dependent upon the physical location of a clinician. For example, if the patient monitoring device **1400** detects an alarm condition while the clinician is already in proximity to the monitoring device, then it may emit no audible alarm or a lower-volume audible alarm. Alarm volume can also be adjusted in other ways based upon detected clinician presence. Similarly, in such a scenario, the patient monitoring device **1400** may be configured not to transmit an alarm to the central monitoring station. In some embodiments, a medical monitoring device does not notify or page other clinicians in case of an alarm if a clinician is already present. Alarm notification behavior of the medical monitoring device can be altered in a variety of ways based upon detected presence of a clinician. A medical monitoring device with clinician proximity awareness can allow a detected clinician to acknowledge his or her presence. As long as clinician presence is detected, the length of expiry of alarms can be changed (e.g., made longer).

In some embodiments, the patient monitoring device **1400** responds to detection of a clinician's presence by changing the language in which textual information is displayed by the monitoring device in accordance with language preferences of the clinician. In some embodiments, the patient monitoring device identifies and executes on-device confirmations that may be required for risk management based upon the detected clinician(s) in proximity to the monitoring device. In some embodiments, the patient monitoring device logs the number of clinician visits to a patient's bedside, the time of presence of each visit, the length of each clinician visit, the response time of clinicians to alarms, etc. A clinician may be permitted to chart parameters measured by the monitoring device to, for example, an electronic medical record with credentials based upon detection of clinician identity. Many other types of actions and/or configuration changes, or combinations of those described herein, can also be caused to automatically be initiated based upon the fact that a clinician has been detected in proximity to the patient monitoring device **1400**.

FIG. **16** illustrates an example graphical user interface **1600** of nurses' station or central patient monitoring station. The graphical user interface **1600** includes features similar to those described with respect to FIG. **9**. For example, the graphical user interface **1600** includes a patient status display area **1610**. The patient status display area **1610** includes a plurality of patient status modules **1612**, each having a graphical status indicator **1614**. The graphical user interface **1600** also includes a patient monitor view area **1620** and a history view area **1630**.

As illustrated in FIG. **9**, the central patient monitoring station includes several patient status display areas, each showing monitoring information from a different patient. Unlike FIG. **9**, however, which shows the status of a number of patients larger than a single nurse could possibly attend to individually, FIG. **16** shows only those patients assigned to a particular clinician. The display of the central patient monitoring station can be automatically updated from that of FIG. **9**, for example, to that of FIG. **16** in recognition of the presence of a clinician. In this way, the clinician can quickly and conveniently check the status of each of his or her assigned patients at a glance by simply approaching the central patient monitoring station without having to actually physically interact with a central patient monitoring station. In addition, the proximity detection features described herein can be used to facilitate assignments of clinicians to patients at the nurses' station. For example, patients can be added to the view of FIG. **16** automatically if the clinician has been detected in proximity to the patient's bedside monitor within some predetermined period of time.

FIG. **17** is a flowchart illustrating a method **1700** for determining when to disable a clinician-specific action that had been previously enabled by a patient monitoring device **1400** based upon the detected presence of the clinician. The method **1700** begins at block **1702** where some clinician-specific action has been previously enabled, as described herein. The method **1700** then proceeds to decision block **1704** and decision block **1708**. For example, the method **1700** may involve detecting whether a previously-detected clinician remains in proximity to a patient monitoring device while simultaneously detecting whether a higher priority clinician arrives in proximity to the patient monitoring device. For example, the process illustrated by decision block **1708** can generate an interrupt signal if the presence of a higher priority clinician is detected.

At decision block **1704**, the processor **1406** executes the detection logic **1408** to determine whether the strength of a signal from the clinician token **1410** has fallen below a signal threshold. This threshold can be the same threshold as used by the decision block **1506** in FIG. **15**. Alternatively, these two thresholds can be different to provide a degree of hysteresis in the detection system to guard against the situation where a clinician token **1410** could be recognized as switching between the present and absent states repeatedly in quick succession if the strength of the signal from the clinician token **1410** happens to be approximately equal to the selected threshold value. If the strength of the signal

from the clinician token **1410** has not fallen below the signal threshold, then the method **1700** returns to block **1702** where the clinician-specific action remains enabled. If, however, the strength of the signal from the clinician token **1410** falls below the threshold used in decision block **1704**, then the method **1700** proceeds to decision block **1706**.

At decision block **1706**, the processor **1406** executes the detection logic **1408** to determine whether the strength of the signal from the clinician token **1410** has fallen below the signal threshold for an absence time that is greater than a time threshold. Thus, the combination of decision blocks **1704** and **1706** determine whether the clinician token has been outside of a particular range for a particular amount of time. In some embodiments, this time threshold can be variable depending upon, for example, the content of information displayed by the medical monitoring device **1400**. For example, if the monitoring device **1400** is displaying sensitive personal information, then the time threshold can be relatively short in order to protect the patient's confidentiality.

If the absence time does not exceed the time threshold used by the decision block **1706**, then the method **1700** returns to block **1702** where the clinician-specific action remains enabled. If, however, the absence time exceeds the time threshold, then the method **1700** proceeds to block **1710**. At block **1710**, the clinician is recognized as no longer being in proximity to the patient monitoring device **1400**. Therefore, the previously-enabled clinician-specific action is disabled. At such time, the patient monitoring device **1400** can return to a state similar to the waiting state **1502** described with respect to FIG. **15**. In some embodiments, the action performed by the patient monitoring device **1400** at block **1710** can substantially reverse any action taken by the monitoring device at block **1510** in FIG. **15**. For example, if the clinician was automatically logged in to the patient monitoring device **1400** when his or her presence was initially detected, then at block **1710**, that clinician can be logged out. Similarly, if the configuration of the monitoring device **1400** was changed based upon the detected clinician's preferences, then, at block **1710**, those configuration changes can be restored to, for example, a default state.

With reference now to the decision block **1708**, the processor **1406** executes the detection logic **1408** to determine whether the presence of a higher priority clinician has been detected. The detection of such a clinician can proceed, for example according to the detection method **1500** described with respect to FIG. **15**. As described herein, each clinician can be assigned a priority value that can act as a tiebreaker criteria to determine the presence of which clinician to recognize when more than one clinician is detected. If no higher priority clinician is detected at decision block **1708**, then the method **1700** returns to block **1702**. If, however, a higher priority clinician is detected at decision block **1708**, then the method **1700** may proceed to block **1710** where the recognition of the presence of the previously-detected clinician is revoked, and the presence of the newly detected higher-priority clinician is recognized.

FIG. **18** is a schematic diagram of a system for enabling a patient monitoring device **1800** to automatically detect the presence of a clinician token **1810**. The patient monitoring device **1800** and the clinician token **1810** can be similar, for example, to the patient monitoring device **1400** and clinician token **1410** described herein with respect to FIG. **14** except as otherwise indicated. In the embodiment illustrated in FIG. **18**, the patient monitoring device **1800** detects the presence of the clinician token **1810** with the assistance of, for example, one or more WiFi access points **1830-1832**. The

WiFi access points **1830-1832** can be advantageously distributed throughout the patient care environment where patient monitoring is occurring. The WiFi access points **1830-1832** can operate based on IEEE 802.11 standards, for example.

The communication module **1802** of the patient monitoring device **1800** can be, for example, a WiFi-enabled radio for communicating with the WiFi access points **1830-1832**. In some embodiments, the clinician token **1810** is a WiFi-enabled RFID tag. By communicating with the WiFi access points **1830-1832**, the patient monitoring device **1800** can triangulate its position relative to that WiFi access points. Likewise, the position of the clinician token **1810** can be triangulated. Thus, the distributed WiFi access points **1830-1832** can be used by, for example, the patient monitoring device **1800** in order to determine the approximate position of the clinician token **1810** with respect to the monitoring device **1800**. In some embodiments, the patient monitoring device **1800** may also communicating directly with the clinician token **1810** in order to, for example, enhance the position approximation determined using the distributed WiFi access points **1830-1832**.

FIG. **19** is a schematic illustration of a patient monitoring device network **1900** having a clinician proximity awareness feature. The patient monitoring device network **1900** can be similar to those shown, for example, in FIGS. **1**, **2**, **6**, and **7**. The patient monitoring device network **1900** includes multiple bedside patient monitors **1902**, **1912**, **1922** for monitoring multiple patients **1906**, **1916**, **1926**. In some embodiments, each of the bedside patient monitors **1902**, **1912**, **1922** is similar to those shown in, for example, FIG. **14** (**1400**) and FIG. **18** (**1800**). The bedside patient monitors **1902**, **1912**, **1922** are capable of detecting the presence of a clinician based upon the clinician tokens **1904**, **1914**, **1924**. The clinician tokens **1904**, **1914**, **1924** can be similar, for example, to those shown in FIG. **14** (**1410**) and FIG. **18** (**1810**).

The patient monitoring device network **1900** also includes a nurses' station **1932** for remotely monitoring each of the patients **1906**, **1916**, **1926**. The nurses' station, or central monitoring station, **1932** can be similar to those described herein. The patient monitoring device network **1900** may also include a registration database **1942**. As described herein, the registration database **1942** can associate unique clinician IDs (e.g., **1414**, **1814**) carried by the clinician tokens **1904**, **1914**, **1924**, **1934** with information for controlling the patient monitoring devices **1902**, **1912**, **1922**, **1932** when the tokens are in the presence of those devices. For example, the registration database **1942** can associate each unique clinician ID with login information, configuration preferences, and predetermined actions for the monitoring devices to perform after recognizing the presence of a clinician.

In the illustrated patient monitoring device network **1900**, each of the patient monitoring devices **1902**, **1912**, **1922**, **1932** can communicate with one another via the network **1950**. In some embodiments, the network **1950** uses open source communications standards in order to facilitate communication between various medical devices. Though not illustrated, the patient monitoring device network **1900** can also include WiFi access points, page transmitters, pagers, and other devices described herein.

FIG. **20** is a schematic drawing of a hospital floor **2000** with distributed WiFi access points **2030-2034** that can be used to estimate the physical locations of medical devices **2002**, **2004**, patients **2010**, **2012**, and clinicians **2014**, **2016**. The WiFi access points **2030-2034**, or other detectors, can

be distributed throughout the hospital floor, or other physical region, in order to provide WiFi coverage throughout the patient care area. In some embodiments, the WiFi access points **2030-2034** have respective coverage areas **2040-2044** that the overlap one another. In some embodiments, the WiFi access points **2030-2034** are populated densely enough so that at least three coverage areas **2040-2044** of the WiFi access points **2030-2034** overlap in substantially every portion of the hospital floor in which it is desired to track the positions of medical devices **2002**, **2004**, patients **2010**, **2012**, and clinicians **2014**, **2016**. The access points **2030-2034** can be mounted, for example, on or in walls, on or in ceilings, etc.

The medical devices **2002**, **2004** can be similar to others described herein. For example, in some embodiments, the medical devices **2002**, **2004** are patient monitoring devices. In some embodiments, the medical devices **2002**, **2004** are fitted with tracking tags or tokens **2006**, **2008**. The tracking tags **2006**, **2008** can be similar to the clinician tokens described herein. In some embodiments, the tracking tags **2006**, **2008** are WiFi-enabled RFID tags, though other types of tracking tags may also be suitable. Each tracking tag **2006**, **2008** can include an equipment ID.

As already discussed herein, the clinicians **2014**, **2016** may carry clinician tokens **2022**, **2024**. The clinician tokens **2022**, **2024** can be similar to those described herein. For example, in some embodiments, the clinician tokens **2014**, **2016** are WiFi-enabled RFID tags. In some embodiments, each patient **2010**, **2012** may also be fitted with a patient token **2018**, **2020**. The patient tokens **2018**, **2020** can be similar to the clinician tokens described herein. In some embodiments, the patient tokens **2018**, **2020** are WiFi-enabled RFID tags. These may be worn as bracelets, or otherwise suitably affixed to the patients. Each patient token **2018**, **2020** can include a patient ID.

The distributed network of WiFi access points **2030-2034** can be used to communicate with the medical device tracking tags **2006**, **2008**, the clinician tokens **2022**, **2024**, and the patient tokens **2018**, **2020** for the purpose of estimating the physical position of each of these tags and tokens in the hospital **2000**. For example, the WiFi access points **2030-2034** can be used to triangulate the position of each tag or token.

While FIG. **20** illustrates a distributed network of WiFi access points **2030-2034** that can be used for detecting the positions of the tracking tags **2006**, **2008**, the clinician tokens **2022**, **2024**, and the patient tokens **2018**, **2020**, other devices can also be used for similar purposes. For example, in some embodiments, the WiFi access points **2030-2034** are eliminated and medical devices **2002**, **2004** with short range transceivers, or other detectors, are used in their place to create an ad hoc network. Each medical device **2002**, **2004** can serve as a node in the ad hoc network, and each node can share information about, for example, the patients **2010**, **2012** and the clinicians **2014**, **2016** around it. In some embodiments, the medical devices **2002**, **2004** are Bluetooth-enabled, though other short range wireless communications standards can also be used.

If the hospital floor **2000** contains a number of medical devices that are arranged densely enough, then the distributed medical devices **2002**, **2004** can serve as a network for tracking the location of, for example, Bluetooth-enabled medical device tracking tags **2006**, **2008**, patient tokens **2018**, **2020**, and clinician tokens **2022**, **2024**. In such an embodiment, the physical location of each tracking tag or token may only be identifiable if it is located within the range of a Bluetooth-enabled medical device. In addition, in some embodiments, the physical location of each tracking tag or token may not be able to be precisely identified, as each Bluetooth-enabled medical device may only be able to determine that the tracking tag or token is located somewhere within the medical device's detection area. Nevertheless, this level of tracking resolution may be sufficient in many cases.

In the embodiment illustrated in FIG. **20**, a location monitoring server may be communicatively coupled to the WiFi access points **2030**, **2034**. The location monitoring server may be configured to track the estimated position of each medical device **2002**, **2004**, each patient **2010**, **2012**, and each clinician **2014**, **2016**. The location monitoring server may include a display to show this location information. In addition, the location monitoring server, or some other device, may execute logic that can be useful in enhancing features offered by the patient monitoring systems described herein. The location monitoring server may also be communicatively coupled to the medical devices **2002**, **2004**.

The system illustrated in FIG. **20** can be used, for example, to enhance the patient monitoring systems described herein. As already discussed, the patient monitoring systems described herein are capable of providing notifications to clinicians when, for example, a monitored patient's physiological parameter (e.g., SpO2, respiratory rate, etc.) triggers an alarm. In some embodiments, the clinician assigned to monitor the patient is notified first by, for example, a page, e-mail, text message, etc. If the first-notifying clinician does not respond within a set period of time, the patient monitoring system may be configured to execute an escalation algorithm whereby one or more additional clinicians are notified of the patient's alarm condition. In some embodiments, the clinician notifications that are sent out when an alarm condition exists can be controlled, at least in part, using location-based rules. For example, location-based rules can be used to determine which clinician is notified of an alarm condition initially, and which clinician, or clinicians, are notified if escalation becomes necessary. The location-based rules can receive as inputs information from the system illustrated in FIG. **20** regarding the physical locations of, for example, patients **2010**, **2012** and/or clinicians **2014**, **2016**.

The location-based rules can be dependent upon, for example, the absolute or relative locations of the patient's **2010**, **2012** and/or the clinicians **2014**, **2016**. For example, if the patient **2010** undergoes an alarm condition, that patient's previously assigned clinician can first be notified so long as he or she is present on the same floor of the hospital (or some other domain). In some embodiments, the clinician located the closest to the patient who is experiencing the alarm condition can be notified regardless of whether the clinician was previously assigned to the patient. In some embodiments, the closest clinician to the patient experiencing the alarm condition can be notified only after the regularly-assigned clinician fails to respond within a certain amount of time. In some embodiments, a nearby clinician is notified of the alarm condition if the alarm condition is particularly urgent and requires immediate attention. Many other location-based rules can also be implemented.

Location-based rules can also be used for controlling whether a clinician is permitted to deactivate an alarm. As disclosed herein, the clinician tokens **2022**, **2024** may include an input module (e.g., **1416**). One use for this input module is to remotely disable an alarm once the clinician has received notification of the alarm and is en route to the patient. However, in some embodiments, a location-based

rule can be put into place that may prevent a clinician from remotely disabling an alarm if the clinician is, for example, more than some threshold distance away from the patient.

The location information provided by the system illustrated in FIG. **20** can also be used to provide alerts to clinicians when a patient **2010**, **2012** strays more than some threshold distance from the monitoring device assigned to the patient. While some examples of location-based rules have been discussed in the context of patient monitoring systems, the information provided by the system illustrated in FIG. **20** can be used to implement a variety of location-based rules for many different kinds of medical devices. Such location-based rules can include, for example, any rule for determining an action to be performed where the selected action is dependent in whole, or in part, upon the estimated physical location of a device, clinician, and/or patient.

In some embodiments, location-based rules can also be provided for configuring the medical devices **2002**, **2004** (e.g., to configure patient monitoring settings). For example, patient monitoring devices of the type described herein are sometimes configured with different physiological parameter alarm limits depending upon the patient ward that they are located in. For example, alarm limits for the pulse rates of neonates should generally be set differently than for the pulse rates of adults. Therefore, it may be desirable to provide a notification to a clinician if an attempt is made to monitor a patient located outside of the nursery using a monitoring device whose alarm limits have been set for neonates. This can be done since the location of the medical device can be detected by the system illustrated in FIG. **20**. Other monitoring device configuration settings can also be recommended to clinicians, or automatically set, based upon the physical location of the monitoring device. In some embodiments, the configuration settings and techniques disclosed in US Patent Publication 2009/0275844, the entire contents of which are hereby incorporated by reference herein, can be controlled using the location-based rules described herein.

FIGS. **21**A-F, FIGS. **22**A-E, and FIGS. **23**A-C illustrate proximity displays **2100**, **2200**, **2300** that feature a multi-sided animation that appears to rotate from a first screen to a preferred screen in response to user proximity. This feature advantageously provides feedback to the user that the monitor has received an identification signal from the user, as described above, and has recognized the user's presence. As examples, the multi-sided presentation may be any of a triangular-shaped, a cubic-shaped or a planar solid having multiple facets and a different screen preference on two or more of the facets. One of ordinary skill will recognize that many other rotating geometric shapes can provide similar user feedback, including un-faceted shapes such as a sphere or cylinder. These multi-sided presentations are described in further detail below.

FIGS. **21**A-F illustrate a proximity display **2100** embodiment that utilizes a rotating triangular solid **2105** to depict transitions between multiple screens that correspond to different display preferences of monitor users that enter or exit proximity to the monitor. In particular, the triangular solid **2105** has a first side **2101**, a second side **2102** and a third side **2103** configured to display different user preferences of patient monitoring information in response to user proximity to the display. Further, the triangular solid **2105** is shown to rotate during a transition between the sides **2101**, **2102**, **2103** so as to provide feedback to a proximate user.

As shown in FIG. **21**A, the first side **2101** relating to a first user is shown in the display **2110**. As shown in FIG. **21**B, when a second user is proximate the display, the monitor identifies the second user, as described with respect to FIG. **7** below, and virtually rotates the triangular solid **2105** from the first side **2101** to the second side **2102**. As shown in FIG. **21**C, the display **2110** then shows the second side **2102**, corresponding to the second user's display preference. As shown in FIG. **21**D, when a third user enters proximity to the monitor, the monitor identifies the third user and virtually rotates the triangular solid **2105** from the second side **2102** to a third side **2103**. As shown in FIG. **21**E, the display **2110** then shows the third side **2103**, corresponding to the third user's display preference. As shown in FIG. **21**F, when the first user is again identified, the display **2110** virtually rotates the triangular solid back to the first side **2101**. In this manner, the sides **2101**, **2102**, **2102** of the triangular solid **2105** are alternatively shown on the display **2110** according to different user preferences and based upon user proximity to the monitor. As described with respect to FIG. **13** if several users are in proximity to the monitor at once, then priority or acknowledgement schemes are utilized to determine which screen to display.

FIGS. **22**A-E illustrate a proximity display **2200** embodiment that utilizes a rotating cube **2205** to depict transitions between multiple screens that correspond to different display preferences of monitor users that enter or exit proximity to the monitor. In particular, the cube **2205** has a first side **2201**, a second side **2202** and a third side **2203** configured to display different user preferences of patient monitoring information in response to user proximity to the display. Further, the cube **2205** is shown to rotate during a transition between the sides **2201**, **2202**, **2203** so as to provide feedback to a proximate user, in a manner similar to that described in detail with respect to FIGS. **21**A-F, above.

FIGS. **23**A-C illustrate a proximity display **2300** embodiment that utilizes a rotating planar solid **2305** to depict transitions between multiple screens that correspond to different display preferences of monitor users that enter or exit proximity to the monitor. In particular, the planar solid **2305** has a first side **2301** and a second side **2302** configured to display different user preferences of patient monitoring information in response to user proximity to the display. Further, the planar solid **2305** is shown to rotate during a transition between the sides **2301**, **2302** so as to provide feedback to a proximate user, in a manner similar to that described in detail with respect to FIGS. **21**A-F and FIGS. **22**A-E, above.

Although some features are described herein with respect to a bedside monitor, a proximity display is applicable to any monitoring device, medical or non-medical and at any location, such as at bedside or at central monitoring, such as a nurse's station. Further, a proximity display is applicable during physiological data collection or other monitor uses, such as historical data review, setting and verification of alarm limits and installation of software updates by medical personnel or equipment maintenance staff, to name a few.

Translation of Medical Communication Protocols to Facilitate Communication Between Devices and Systems

Healthcare costs have been increasing and the demand for reasonably-priced, high-quality patient care is also on the rise. Health care costs can be reduced by increasing the effectiveness of hospital information systems. One factor which may affect the efficacy of a health institution is the extent to which the various clinical computer systems employed at the health institution can interact with one another to exchange information.

Hospitals, patient care facilities, and healthcare provider organizations typically include a wide variety of different clinical computer systems for the management of electronic

healthcare information. Each of the clinical computer systems of the overall IT or management infrastructure can help fulfill a particular category or aspect of the patient care process. For example, a hospital can include patient monitoring systems, medical documentation and/or imaging systems, patient administration systems, electronic medical record systems, electronic practice management systems, business and financial systems (such as pharmacy and billing), and/or communications systems, etc.

The quality of care in a hospital or other patient care facility could be improved if each of the different clinical computer systems across the IT infrastructure were able to effectively communicate with each other. This could allow for the exchange of patient data that is collected by one clinical computer system with another clinical computer system that could benefit from such patient data. For example, this may allow decisions relating to patient care to be made, and actions to be taken, based on a complete analysis of all the available information.

In current practice, individual clinical computer systems can be, and often are, provided by different vendors. As a result, individual clinical computer systems may be implemented using a proprietary network or communication infrastructure, proprietary communication protocols, etc.; the various clinical computer systems used in the hospital cannot always effectively communicate with each other.

Medical device and medical system vendors sometimes develop proprietary systems that cannot communicate effectively with medical devices and systems of other vendors in order to increase their market share and to upsell additional products, systems, and/or upgrades to the healthcare provider. Thus, healthcare providers are forced to make enterprise or system-wide purchase decisions, rather than selecting the best technology available for each type of individual clinical computer system in use.

One example where this occurs is in the area of life-saving technology available for patient monitoring. For example, many different bedside devices for monitoring various physiological parameters are available from different vendors or providers. One such provider may offer a best-in-class device for monitoring a particular physiological parameter, while another such provider may offer the best-in-class device for another physiological parameter. Accordingly, it may be desirable in some circumstances for a hospital to have the freedom to use monitoring devices from more than one manufacturer, but this may not be possible if devices from different manufacturers are incapable of interfacing and exchanging patient information. Accordingly, the ability to provide reasonably-priced, high-quality patient care can be compromised. In addition, since each hospital or patient care facility may also implement its own proprietary communication protocols for its clinical computer network environment, the exchange of information can be further hindered.

The Health Level Seven ("HL7") protocol has been developed to provide a messaging framework for the communication of clinical messages between medical computer systems and devices. The HL7 communication protocol specifies a number of standards, guidelines, and methodologies which various HL7-compliant clinical computer systems can use to communicate with each other.

The HL7 communication protocol has been adopted by many medical device manufacturers. However, the HL7 standard is quite flexible, and merely provides a framework of guidelines (e.g., the high-level logical structure of the messages); consequently, each medical device or medical system manufacturer or vendor may implement the HL7 protocol somewhat differently while still remaining HL7-compliant. For example, the format of the HL7 messages can be different from implementation to implementation, as described more fully herein. In some cases, the HL7 messages of one implementation can also include information content that is not included in messages according to another HL7 implementation. Accordingly, medical devices or clinical computer systems that are all HL7-compliant still may be unable to communicate with each other.

Consequently, what is needed is a module that can improve the communication of medical messages between medical devices or systems that use different allowed implementations of an established communication protocol (e.g., HL7), thereby increasing the quality of patient care through the integration of multiple clinical computer systems.

FIG. **24**A illustrates a first medical device **2405** and a second medical device **2410** that communicate with one another via a translation module **2415**. The first medical device **2405** is configured to transmit and receive messages according to a first allowed format or implementation of an accepted electronic medical communication protocol, while the second medical device **2410** is configured to transmit and receive messages according to a second allowed format or implementation of the electronic medical communication protocol. In some embodiments, the first and second protocol formats are different implementations of the HL7 communication protocol. Other electronic medical communication protocols besides HL7 can also be used.

The translation module **2415** receives input messages having the first protocol format from the first medical device **2405** and generates output messages to the second medical device **2410** having the second protocol format. The translation module **2415** also receives input messages having the second protocol format from the second medical device **2410** and generates output messages to the first medical device **2405** having the first protocol format. Thus, the translation module **2415** enables the first and second medical devices **2405**, **2410** to effectively and seamlessly communicate with one another without necessarily requiring modification to the communication equipment or protocol implemented by each device.

In certain embodiments, the translation module **2415** determines the protocol format expected by an intended recipient of the input message based on, for example, the information in the input message or by referencing a database that stores the protocol format used by various devices, and then generates the output message based on the protocol format used by the intended recipient device or system. The output message can be generated based upon a comparison with, and application of, a set of translation rules **2420** that are accessible by the translation module **2415**.

The translation rules **2420** can include rules that govern how to handle possible variations between formatting implementations within a common protocol. Examples of variations in formatting implementation of an electronic medical communication protocol include, for example, the delimiter or separator characters that are used to separate data fields, whether a particular field is required or optional, the repeatability of portions of the message (e.g., segments, fields, components, sub-components), the sequence of portions of the message (e.g., the order of fields or components), whether a particular portion of a message is included, the length of the message or portions of the message, and the data type used for the various portions of the message.

In certain embodiments, the translation rules **2420** define additions, deletions, swappings, and/or modifications that should be performed in order to "translate" an input message

that adheres to a first HL7 implementation into an output message that adheres to a second HL7 implementation. The output message can have, for example, different formatting than the input message, while maintaining all, or a portion of, the substance or content of the input message.

In addition to translating between different implementations of a common electronic medical communication protocol (e.g., different formatting of HL7 messages), the translation module **2415** can also be configured to translate between input and output messages adhering to different communication protocols. In some embodiments, the translation module **2415** is capable of responding to and translating messages from, for example, one medical communication protocol to a separate medical communication protocol. For example, the translation module **2415** can facilitate communication between messages sent according to the HL7 protocol, the ISO 11073 protocol, other open protocols, and/or proprietary protocols. Accordingly, an input message sent according to the HL7 protocol can be translated to an output message according to a different protocol, or vice-versa.

The operation of the translation module **2415** and the translation rules **2420** will be described in more detail below. Various embodiments of system architectures including the translation module **2415** will now be described.

In certain embodiments, the first medical device **2405**, the second medical device **2410**, and the translation module **2415** are communicatively coupled via connection to a common communications network. In some embodiments, the translation module **2415** can be communicatively coupled between the first medical device **2405** and the second medical device **2410** (with or without a communications network) such that all messages between the first and second medical devices **2405**, **2410** are routed through the translation module **2415**. Other architectures are also possible.

The first and second medical devices **2405**, **2410** and the translation module **2415** can be included in, for example, a portion of the physiological monitoring system **200** of FIG. **2** or the clinical network environment **600** of FIG. **6** described above. In certain embodiments, the portion of the physiological monitoring system **200** comprises a portion of a messaging sub-system of the physiological monitoring system **200** for supporting the exchange of data between the various clinical computer systems used in the hospital.

In certain embodiments, the translation module **2415** can facilitate communication across multiple networks within a hospital environment. In other embodiments, the translation module **2415** can facilitate communication of messages across one or more networks extending outside of the hospital or clinical network environment. For example, the translation module **2415** can provide a communications interface with banking institutions, insurance providers, government institutions, outside pharmacies, other hospitals, nursing homes, or patient care facilities, doctors' offices, and the like.

In some embodiments, the translation module **2415** of FIG. **24** can be a component of, for example, the patient monitoring system **200** described herein. For example, the translation module **2415** can be communicatively coupled with the hospital network **220** illustrated in FIG. **2**. In such embodiments, the translation module **2415** can facilitate the exchange of patient monitoring information, including, for example, physiological parameter measurements, physiological parameter trend information, and physiological parameter alarm conditions between bedside medical monitor devices, nurses' monitoring stations, a Hospital or Clinical Information System (which may store Electronic Medical Records), and/or many other medical devices and systems. The translation module **2415** can enable seamless communication between different medical devices and systems, each of which may use a different implementation of an electronic medical communication protocol such as, for example, the HL7 communication protocol, within a clinical or hospital network environment.

In certain embodiments, the translation module **2415** can also facilitate communication between a first medical device that is part of the patient monitoring sub-system and a second medical device that is not part of, or is external to, the patient monitoring system **200**. As such, the translation module **2415** can be capable of responding to externally-generated medical messages (such as patient information update messages, status query messages, and the like from an HIS or CIS) and generating external reporting messages (such as event reporting messages, alarm notification messages, and the like from patient monitors or nurses' monitoring stations).

In another embodiment, first and second medical devices **2405**, **2410** communicate with each other over a communication bus **2421**. Communication bus **2421** can include any one or more of the communication networks, systems, and methods described above, including the Internet, a hospital WLAN, a LAN, a personal area network, etc. For example, any of the networks describe above with respect to FIGS. **1**, **2**, **6**, **7**, **19**, etc. can be used to facilitate communication between a plurality of medical devices, including first and second medical devices **2405**, **2410**, discussed above. One such embodiment is illustrated in FIG. **24**B.

In FIG. **24**B, first medical device **2405** provides a message to the communication bus **2421**. The message is intended for receipt by the second medical device **2410**; however, because first and second medical devices **2405**, **2410** communicate according to different communication protocol format, second medical device **2410** is unable to process the message.

Translation module **2415** monitors the communication bus **2421** for such messages. Translation module receives the message and determines that first medical device **2405** is attempting to communicate with second medical device **2410**. Translation module **2415** determines that message translation would facilitate communication between first and second medical devices **2405**, **2410**. Translation module **2415** therefore utilizes an appropriate translation rule stored in a translation module **2420**. Translation module **2420** can include a memory, EPROM, RAM, ROM, etc.

The translation module **2415** translates the message from the first medical device **2405** according to any of the methods described herein. Once translated, the translation module **2415** delivers the translated message to the communication bus **2421**. The second medical device **2410** receives the translated message and responds appropriately. For example, the second medical device may perform a function and/or attempt to communication with the first medical device **2405**. The translation module **2415** facilitates communication from the second medical device **2410** to the first medical device **2405** in a similar manner.

The first medical device **2405** and the second medical device **2410** can be, for example, any of the medical devices or systems communicatively coupled to the hospital network **222** illustrated in FIG. **2**. These medical devices or systems can include, for example, point-of-care devices (such as bedside patient monitors), data storage units or patient record databases, hospital or clinical information systems, central monitoring stations (such as a nurses' monitoring

station), and/or clinician devices (such as pagers, cell phones, smart phones, personal digital assistants (PDAs), laptops, tablet PCs, personal computers, pods, and the like).

In some embodiments, the first medical device **2405** is a patient monitor for communicatively coupling to a patient for tracking a physiological parameter (e.g., oxygen saturation, pulse rate, blood pressure, etc.), and the second medical device **2410** is a hospital information system ("HIS") or clinical information system ("CIS"). In some embodiments, the patient monitor can communicate physiological parameter measurements, physiological parameter alarms, or other physiological parameter measurement information generated during the monitoring of a patient to the HIS or CIS for inclusion with the patient's electronic medical records maintained by the HIS or CIS.

In some embodiments, the first medical device **2405** is an HIS or CIS and the second medical device **2410** is a nurses' monitoring station, as described herein. However, the translation module **2415** can facilitate communication between a wide variety of medical devices and systems that are used in hospitals or other patient care facilities. For example, the translation module **2415** can facilitate communication between patient physiological parameter monitoring devices, between a monitoring device and a nurses' monitoring station, etc.

Using the translation module **2415**, a patient monitoring sub-system, such as those described herein (e.g., physiological monitoring system **200**), can push data to the HIS or pull data from the HIS even if the HIS uses a different implementation of the HL7 protocol, or some other electronic medical communication protocol.

In certain embodiments, the patient monitoring sub-system can be configured to push/pull data at predetermined intervals. For example, a patient monitor or clinician monitoring station can download patient data automatically from the HIS at periodic intervals so that the patient data is already available when a patient is connected to a patient monitor. The patient data sent from the HIS can include admit/discharge/transfer ("ADT") information received upon registration of the patient. ADT messages can be initiated by a hospital information system to inform ancillary systems that, for example, a patient has been admitted, discharged, transferred or registered, that patient information has been updated or merged, or that a transfer or discharge has been canceled.

In other embodiments, the patient monitoring sub-system can be configured to push/pull data to/from the HIS only when the HIS is solicited by a query. For example, a clinician may make a request for information stored in a patient's electronic medical records on the HIS.

In still other embodiments, the patient monitoring sub-system can be configured to push/pull data to/from the HIS in response to an unsolicited event. For example, a physiological parameter of a patient being monitored can enter an alarm condition, which can automatically be transmitted to the HIS for storing in the patient's electronic medical records. In yet other embodiments, any combination of the above methods or alternative methods for determining when to communicate messages to and from the HIS can be employed.

Example system architectures and example triggers for the communication of messages involving the translation module **2415** have been described. Turning now to the operation of the translation module, FIGS. **25**A-**25**D illustrate an example medical message at different phases or

steps of a translation process. The translation process will be described in more detail below in connection with FIGS. **26**, **27**A and **27**B.

FIG. **25**A illustrates an example ADT input message **2505** received by the translation module **2415** from an HIS. The ADT input message **2505** is implemented according to the HL7 communication protocol and contains information related to the admission of a patient to a hospital. The ADT message **2505** includes multiple segments, including a message header segment **2506**, an event segment, a patient identification segment, a patient visit segment, role segments, a diagnosis segment, and multiple custom segments.

In some embodiments, the message header ("MSH") segment **2506** defines how the message is being sent, the field delimiters and encoding characters, the message type, the sender and receiver, etc. The first symbol or character after the MSH string can define the field delimiter or separator (in this message, a "caret" symbol). The next four symbols or characters can define the encoding characters. The first symbol defines the component delimiter ("~"), the second symbol defines the repeatable delimiter ("|"), the third symbol defines the escape delimiter ("\"), and the fourth symbol defines the sub-component delimiter ("&"). All of these delimiters can vary between HL7 implementations.

In some embodiments, the example header segment **2506** further includes the sending application ("VAFC PIMS"), the receiving application ("NPTF-508"), the date/time of the message ("20091120104609-0600"), the message type ("ADT~A01"), the message control ID ("58103"), the processing ID ("P"), and the country code ("USA"). As represented by the consecutive caret symbols, the header segment also contains multiple empty fields.

FIG. **25**B illustrates the message header segment **2506** after it has been parsed into fields or elements based on an identified field delimiter (the caret symbol). In certain embodiments, the parsed input message comprises an XML message that is configured to be transformed according to extensible stylesheet language transformation (XSLT) rules.

In certain embodiment, the parsed input message can be encoded. FIG. **25**C illustrates the parsed message header segment of the input message after being encoded (e.g., using a Unicode Transformation Format-8 ("UTF-8") encoding scheme).

The encoded message header segment shows some of the various data types that can be used in the message. For example, the sending application ("VAFC PIMS") of the third parsed field and the receiving application ("NPTF-**508**") of the fifth parsed field are represented using a hierarchic designator ("HD") name data type. The date/time field (the seventh parsed field) is represented using the time stamp ("TS") data type. The processing ID field (the eleventh parsed field) is represented using the processing type ("PT") data type. The fields that do not include a data type identifier are represented using the string ("ST") data type. Other possible data types include, for example, coded element, structured numeric, timing quantity, text data, date, entry identifier, coded value, numeric, and sequence identification. The data types used for the various fields or attributes of the segments can vary between formatting implementations.

FIG. **25**D illustrates an example output message **2510** from the translation module **2415** based on the example input message **2505** of FIG. **25**A. The output message **2510** includes a message acknowledgement segment **2512**.

Turning to the operation of the translation module, the translation module **2415** can, for example, create, generate,

or produce an output message that is reflective of the input message based on an application of the set of translation rules **2420**. In some embodiments, the translation module **2415** can, for example, translate, transform, convert, reformat, configure, change, rearrange, modify, adapt, alter, or adjust the input message based on a comparison with, and application of, the set of translation rules **2420** to form the output message. In some embodiments, the translation module **2415** can, for example, replace or substitute the input message with an output message that retains the content of the input message but has a new formatting implementation based upon a comparison with, and application of, the set of translation rules **2420**.

FIG. **26** illustrates a translation process **2600** for generating an output message based on an input message and a comparison with the set of translation rules **2420** associated with the translation module **2415**. The translation process **2600** starts at block **2602** where the translation module **2415** receives an input message from a first medical device.

At block **2604**, the translation module **2415** determines the formatting implementation of the input message and the formatting implementation to be used for the output message. In certain embodiments, the input message can include one or more identifiers indicative of the formatting implementation. In some embodiments, the determination of the formatting implementation can be made, for example, by analyzing the message itself by identifying the delimiter or encoding characters used, the field order, the repeatability of segments, fields, or components, the data type of the fields, or other implementation variations. In certain embodiments, the translation module **2415** can separate or parse out the formatting from the content of the message (as shown in FIG. **25**B) to aid in the determination of the formatting implementation. In some embodiments, the translation module **2415** determines the formatting implementation of the input message by referencing a database that stores the implementation used by each device with which the translation module **2415** has been configured to interface.

In certain embodiments, the determination of the formatting implementation required by the output message can also be determined from the input message. For example, the input message can include a field that identifies the intended recipient application, facility, system, device, and/or destination. The input message can alternatively include a field that identifies the type of message being sent (e.g., ADT message) and the translation module **2415** can determine the appropriate recipient from the type of message being sent and/or the sending application, device, or system. The translation module **2415** can then determine the formatting implementation required by the intended recipient of the input message.

At decision block **2605**, the translation module **2415** determines whether a rule set has been configured for the translation from the identified formatting implementation of the input message to the identified formatting implementation to be used for the output message. The rule set may have been manually configured prior to installation of the translation module software or may have been automatically configured prior to receipt of the input message. If a rule set has already been configured, then the translation process **2600** continues to block **2606**. If a rule set has not been configured, then a rule set is configured at block **2607**. The configuration of the rule set can be performed as described below in connection with FIGS. **28** and **29**A-**29**D. The translation process **2600** then continues to block **2608**.

At block **2606**, the translation module **2415** identifies the pre-configured rules from the set of translation rules **2420** that govern translation between the determined formatting implementation of the input message and the formatting implementation of the output message. In some embodiments, the identification of the pre-configured rules can be made manually.

At block **2608**, the translation module **2415** generates an output message based on the configured rule set(s) of the translation rules **2420**. In certain embodiments, the output message retains all, or at least a portion of, the content of the input message but has the format expected and supported by the intended recipient of the input message.

The translation rules **2420** can include, for example, unidirectional rules and/or bidirectional rules. A unidirectional rule is one, for example, that may be applied in the case of a message from a first medical device (e.g., **2405**) to a second medical device (e.g., **2410**) but is not applied in the case of a message from the second medical device to the first medical device. For example, a unidirectional rule could handle a difference in the delimiters used between fields for two different formatting implementations of, for example, the HL7 communication protocol. The translation module **2415** can apply a field delimiter rule to determine if the field delimiter is supported by the intended recipient of the input message. If the field delimiter of the input message is not supported by the intended recipient, the field delimiter rule can replace the field delimiter of the input message with a field delimiter supported by the intended recipient.

For example, an input message from an input medical device can include a formatting implementation that uses a "caret" symbol ("^") as the field delimiter or separator. However, the formatting implementation recognized by the intended recipient medical device may use a "pipe" symbol ("|") as the field delimiter. The translation module **2415** can identify the field delimiter symbol used in the formatting implementation recognized by the intended recipient medical device from the set of translation rules **2420** and generate an output message based on the input message that uses the pipe field delimiter symbol instead of the caret field delimiter symbol used in the input message. The rule to substitute a pipe symbol for a caret symbol would, in this case, only apply to messages that are sent to a recipient device that recognizes the pipe symbol as a field delimiter. This rule could be accompanied by a complementary rule that indicates that a caret symbol should be substituted for a pipe symbol in the case of a message that is intended for a recipient device that is known to recognize the caret symbol as the field delimiter.

Another unidirectional rule can handle the presence or absence of certain fields between different formatting implementations. For example, an input message from an input medical device can include fields that would not be recognized by the intended recipient medical device. The translation module **2415** can generate an output message that does not include the unrecognized or unsupported fields. In situations where an input message does not include fields expected by the intended recipient medical device, the set of translation rules **2420** can include a rule to insert null entries or empty " " strings in the fields expected by the intended recipient medical device and/or to alert the recipient device of the absence of the expected field. The sender device may also be notified by the translation module **2415** that the recipient device does not support certain portions of the message.

Other unidirectional rules can facilitate, for example, the conversion of one data type to another (for example, string ("ST") to text data ("TX") or structured numeric ("SN") to numeric ("NM")), and the increase or decrease in the length

of various portions of the message. Unidirectional rules can also be used to handle variations in repeatability of portions of the message. For example, the translation module **2415** can apply a field repeatability rule to repeated instances of a segment, field, component, or sub-component of the message to determine how many such repeated instances are supported by the recipient device, if any, and deleting or adding any repeated instances if necessary. For example, a phone number field of a patient identification segment can be a repeatable field to allow for entry of home, work, and cell phone numbers.

Bidirectional rules can also be used. Such rules may apply equally to messages between first and second medical devices (e.g., **2405**, **2410**) regardless of which device is the sender and which is the recipient. A bidirectional rule can be used to handle changes in sequence, for example. In certain implementations, an input message from an input medical device can include a patient name field, or fields, in which a first name component appears before a last name component. However, the intended recipient medical device may be expecting an implementation where the last name component appears before the first name component. Accordingly, the set of translation rules **2420** can include a bidirectional rule to swap the order of the first and last name components when communicating between the two medical devices, or between the two formatting implementations. In general, field order rules can be applied to determine whether the fields, components, or sub-components are in the correct order for the intended recipient and rearranging them if necessary. Other bidirectional rules can be included to handle, for example, other sequential variations between formatting implementations or other types of variations.

The translation rules **2420** can also include compound rules. For example, a compound rule can include an if-then sequence of rules, wherein a rule can depend on the outcome of another rule. Some translation rules **2420** may employ computations and logic (e.g., Boolean logic or fuzzy logic), etc.

As discussed above, the messages communicated over the hospital-based communication network can employ the HL7 protocol. FIGS. **27**A and **27**B illustrate translation processes **2700**A, **2700**B in which HL7 messages are communicated between a HIS and a medical device over a hospital-based communications network or a clinical network. The translation processes **2700**A, **2700**B will be described with the assumption that the rules governing "translation" between the first and second HL7 formats have already been configured.

FIG. **27**A illustrates a translation process **2700**A in which the translation module **2415** facilitates communication of an HL7 message, such as the ADT message of FIG. **25**A, from an HIS having a first HL7 format to an intended recipient medical device, such as a patient monitor or a clinician monitoring station, having a second HL7 format.

The translation process **2700**A starts at block **2701**, where the translation module **2415** receives an input message having a first HL7 format from the HIS. In certain embodiments, the input message includes information regarding, for example, the admission of a patient and/or patient identification and patient medical history information from an electronic medical records database.

At block **2703**, the translation module **2415** determines the formatting implementation of the input message and the formatting implementation to be used for the output message. These determinations can be made in a similar manner to the determinations discussed above in connection with block **2604** of FIG. **26**.

At block **2705**, the translation module **2415** identifies the rules that govern translation between the determined HL7 format of the input message and the HL7 format of the output message and generates an output message having the second HL7 format based on the identified rules. In certain embodiments, the output message retains the content of the input message sent by the HIS but has the format expected and supported by the intended recipient of the input message.

At block **2707**, the translation module **2415** can output the output message to the intended recipient over the hospital-based communications network. In certain embodiments, the intended recipient can transmit an acknowledgement message back to the hospital information system acknowledging successful receipt or reporting that an error occurred.

FIG. **27**B illustrates a translation process **2700**B in which the translation module **2415** facilitates communication of an HL7 message from a medical device, such as a patient monitor, having a first HL7 format to an HIS having a second HL7 format. For example, the patient monitor can transmit reporting event data m such as patient alarm data, to the HIS to store in the patient's electronic medical records.

The translation process **2700**B starts at block **2702**, where the translation module **2415** receives an input message having a first HL7 format from the medical device. In certain embodiments, the input message includes patient monitoring data or alarm data regarding one or more physiological parameters of the patient being monitored for storage in an electronic medical records database associated with the HIS.

At block **2704**, the translation module **2415** determines the formatting implementation of the input message and the formatting implementation to be used for the output message. These determinations can be made in a similar manner to the determinations discussed above in connection with block **2604** of FIG. **26**.

At block **2706**, the translation module **2415** identifies the rules that govern translation between the determined HL7 format of the input message and the HL7 format of the output message and generates an output message having the second HL7 format based on the identified rules. In certain embodiments, the output message retains the content of the input message sent by the medical device but has the format expected and supported by the HIS.

At block **2708**, the translation module **2415** can output the output message to the hospital information system over the hospital-based communications network. In certain embodiments, the HIS can transmit an acknowledgement message back to the medical device acknowledging successful receipt or reporting that an error occurred.

FIGS. **26**, **27**A and **27**B described the operation of the translator module **2415**. FIGS. **28** and **29**A-**29**D will be used to illustrate the description of the configuration of the translation rules **2420**.

The translation rules **2420** can be implemented as one or more stylesheets, hierarchical relationship data structures, tables, lists, other data structures, combinations of the same, and/or the like. In certain embodiments, the translation rules **2420** can be stored in local memory within the translation module **2415**. In other embodiments, the translation rules **2420** can be stored in external memory or on a data storage device communicatively coupled to the translation module **2415**.

The translation module **2415** can include a single rule set or multiple rule sets. For example, the translation module **2415** can include a separate rule set for each medical device/system and/or for each possible communication pair

of medical devices/systems coupled to the network or capable of being coupled to the network. In some embodiments, the translation module **2415** can include a separate rule set for each possible pair of formatting implementations that are allowed under a medical communication protocol such as, for example, the HL7 protocol.

In certain embodiments, the translation rules **2420** can be manually inputted using, for example, the messaging implementation software tool **2800** illustrated in FIG. **28**. For example, the software developer for a particular hospital network can determine the protocol message formats used by the devices and/or systems that are or can be coupled to the hospital network and then manually input rules to facilitate "translation" between the various protocol message formats supported or recognized by the devices and/or systems.

FIG. **28** illustrates an example screenshot from a messaging implementation software tool **2800** for manually configuring translation rules **2420** to be used by the translation module **2415**. The screenshot from the messaging implementation software tool **2800** illustrates various parameters that may differ between formatting implementations of an electronic medical communication protocol, such as HL7. The screenshot also includes areas where a user can input information that defines, or is used to define, translation rules for converting between different HL7 implementations. In some embodiments, the messaging implementation software tool **2800** stores a variety of pre-configured rule sets based, for example, on known communication protocol implementations of various medical devices. In such embodiments, a user may configure one or more translation rules **2420** to be used in communications involving such devices by entering identification information, such as the device manufacturer, model number, etc. Based on this identification information, the messaging implementation tool **2800** can identify a pre-configured set of translation rules for communication with that device.

In other embodiments, the translation rules **2420** can be automatically generated. For example, the automatic generation of a new set, or multiple sets, of rules can be triggered by the detection of a newly recognized "communicating" medical device or system on a network. In certain embodiments, the automatic generation of a new set or multiple sets of rules can occur at the time a first message is received from or sent to a new "communicating" medical device or system coupled to the network. In still other embodiments, the automatic generation of rule sets includes updating or dynamically modifying a pre-existing set of rules.

The automatic generation of translation rule sets can be carried out in a variety of ways. For example, in some embodiments, the translation module **2415** can automatically initiate usage of a pre-configured set of translation rules **2420** based upon, for example, the make and model of a new device that is recognized on the network. In certain embodiments, the translation module **2415** can request one or more messages from the new device or system and then analyze the messages to determine the type of formatting being implemented, as illustrated by the automatic rule configuration process **2900**A of FIG. **29**A. The automatic rule configuration process **2900**A starts at block **2901**, where the translation module **2415** receives one or more messages from a detected medical device or system on the network. The messages can be received upon transmission to an intended recipient medical device or system or in response to a query sent by the translation module **2415** or another medical device or system coupled to the network.

At block **2903**, the translation module **2415** determines the protocol of the one or more received messages by, for example, analyzing the message or by consulting a database that indicates what communication protocol/format is implemented by each medical device or system on the network. In certain embodiments, the translation module **2415** is configured to handle medical messages implemented using a single common protocol, such as HL7. Accordingly, if a determination is made that the received messages are implemented using a non-supported or non-recognized protocol, the translation module can ignore the messages received from the detected medical device or system, output an alert or warning, or allow the messages to be sent without being translated.

At block **2905**, the translation module **2415** determines the formatting implementation of the received message(s). In certain embodiments, the received messages can include one or more identifiers indicative of the formatting implementation. In other embodiments, the determination of the formatting implementation can be made, for example, by analyzing the message itself by checking field order, the delimiter or encoding characters used, or other implementation variations. In certain embodiments, the translation module **2415** can separate or parse out the formatting from the content of the message to aid in the determination of the formatting implementation.

At block **2907**, the translation module **2415** configures one or more rules or rule sets to handle messages received from and/or sent to the detected medical device or system. In certain embodiments, the configuration of the rules involves the creation or generation of new rules. In other embodiments, the configuration of the rules involves the alteration or updating of existing rules. The configured rules or rule sets can be included with the translation rules **2420**. If a set of rules already exists for the formatting implementation used by the new device or system, then the configuration of new translation rules may not be required. Instead, existing translation rules can be associated with the new device or system for use in communication involving that device or system. In other embodiments, the translation module **2415** can create a new set of rules geared specifically for the new device or system or can modify an existing set of rules based on subtle formatting variations identified.

In other embodiments, the translation module **2415** can generate test message(s) that may be useful in identifying the communication protocol and implementation used by a device or system. For example, the translation module can generate test messages to cause the newly detected device or system to take a particular action (e.g., store information) and then query information regarding the action taken by the newly detected device to determine whether or how the test message was understood. This is illustrated by the automatic rule configuration process **2900**B of FIG. **29**B.

The automatic rule configuration process **2900**B starts at block **2902**, where the translation module **2415** transmits one or more test, or initialization, messages to a remote device or system detected on a network. The test messages can be configured, for example, to instruct the remote device or system to take a particular action (e.g., store patient information). In certain embodiments, the test messages can be configured to generate a response indicative of the type of formatting recognized or supported by the remote device or system. In other embodiments, the test messages can be configured such that only devices or systems supporting a particular formatting implementation will understand and properly act on the test messages.

At block **2904**, the translation module **2415** queries the remote device or system to receive information regarding the action taken based on the test message sent to the remote device or system to determine whether the test message was understood. For example, if the test message instructed the remote device or system to store patient information in a particular location, the translation module **2415** can query the information from the location to determine whether the test message was understood. If the test message was not understood, the translation module **2415** can, for example, continue sending test messages of known formatting implementations until a determination is made that the test message has been understood.

At block **2906**, the translation module **2415** determines the protocol and formatting implementation based on the information received. As an example, in certain embodiments, the test message can include an instruction to store patient name information. The test message can include a patient name field having a first name component followed by a surname component. The translation module **2415** can then query the remote device or system to return the patient surname. Depending on whether the patient surname or the first name is returned, this query can be useful in determining information about the order of fields in the formatting implementation being used by the remote device or system. As another example, the test messages can instruct the detected device or system to store repeated instances of a component. The translation module **2415** can then query the device or system to return the repeated instances to see which, if any, were stored. This repeatability information can also be useful in determining whether certain fields are allowed to be repeated in the formatting implementation being used by the remote device for system, and, if so, how many repeated instances are permitted.

At block **2908**, the translation module **2415** configures one or more rules to handle messages received from and/or sent to the detected medical device or system. For example, the rules can convert messages from the message format used by a first medical device to that used by a second medical device, as described herein. In certain embodiments, the configuration of the rules involves the creation or generation of new rules. In other embodiments, the configuration of the rules involves the alteration or updating of existing rules. If a set of rules already exists for the formatting implementation used by the new device or system, then the configuration of new translation rules may not be required. Instead, existing translation rules can be associated with the new device or system for use in communication involving that device or system.

FIGS. **29**C and **29**D illustrate automatic rule configuration processes performed by the translation module **2415** for messages utilizing the HL7 protocol. The HL7 protocol can be used, for example, to communicate electronic messages to support administrative, logistical, financial, and clinical processes. For example, HL7 messages can include patient administration messages, such as ADT messages, used to exchange patient demographic and visit information across various healthcare systems.

The automatic rule configuration process **2900**C illustrated in FIG. **29**C is similar to the process **2900**A illustrated in FIG. **29**A. At block **2911**, the translation module **2415** receives one or more messages from an HL7 medical device. At block **2915**, the translation module **2415** determines the formatting implementation of the HL7 medical device from the one or more messages received. As discussed above, the determination of the formatting implementation can be made, for example, by checking field order or sequence, field delimiter characters, repeatability, cardinality, and other HL7 implementation variations.

At block **2917**, the translation module **2415** configures one or more rules to handle messages received from and/or sent to the HL7 medical device. In certain embodiments, the configuration of the rules involves the creation or generation of new rules for the detected formatting implementation. In other embodiments, the configuration of the rules involves the dynamic alteration or updating of existing rules. If a set of rules already exists for the formatting implementation used by the new HL7 medical device, then the configuration of new translation rules may not be required. Instead, existing translation rules can be associated with the new HL7 medical device for use in communication involving that device.

The automatic rule configuration process **2900**D illustrated in FIG. **29**D is similar to the process **2900**B illustrated in FIG. **29**B. At block **2912**, the translation module **2415** transmits one or more test, dummy, or initialization messages to an HL7 medical device. In other embodiments, the translation module **2415** can cause one or more test messages to be transmitted to the new HL7 medical device from another HL7 medical device. As described above, the test messages can include messages having known HL7 formats configured to determine whether the HL7 device understands the test messages. The test messages can include test ADT messages, for example.

At block **2914**, the translation module **2415** queries the HL7 medical device to receive information regarding an action taken or information stored in response to the test message. At block **2916**, the translation module **2415** determines the formatting implementation of the HL7 device based on the information received. In certain embodiments, the translation module **2415** can analyze the information received to determine whether the test message or messages were properly understood. If none of the test messages were properly understood, the translation module **2415** can send additional test messages having other known HL7 formats and repeat blocks **2914** and **2916**.

At block **2918**, the translation module **2415** configures one or more translation rules to handle messages received from and/or sent to the detected HL7 medical device. In certain embodiments, the configuration of the translation rules involves the creation or generation of new translation rules. In other embodiments, the configuration of the rules involves the alteration or updating of existing rules. If a set of translation rules already exists for the formatting implementation used by the new HL7 medical device, then the configuration of new translation rules may not be required. Instead, existing translation rules can be associated with the new HL7 medical device for use in communication involving that HL7 medical device.

The automatic rule configuration processes described above can be triggered by the detection of a network device or system by the translation module **2415**. The medical devices referred to in FIGS. **29**A-**29**D can include any of the devices or systems illustrated in FIG. **2** and discussed above.

In some embodiments, the automatic generation of translation rules can advantageously occur post-installation and post-compilation of the messaging sub-system software, which includes the translation module **2415**. In certain embodiments, the automatic generation or dynamic modification of the translation rules **2420** can occur without having to recompile or rebuild the translation module software. This feature can be advantageous in terms of effi-

ciently complying with U.S. Food and Drug Administration ("FDA") requirements regarding validation of software used in healthcare environments.

Take, for example, a situation where a medical device manufacturer plans to use the translation module **2415** to facilitate communication between a particular medical device or system that is to be installed in a hospital (e.g., a patient monitoring system, as described herein), or other patient care facility, and other devices or systems that are already installed at the hospital (e.g., the HIS or CIS). Any software required for the operation of the new medical device to be installed may be at least partially validated for FDA compliance prior to installation at the hospital despite the fact that, for example, the HL7 implementations of other existing devices or systems at the hospital may still be unknown. For example, any aspects of the software for the new medical device that are dependent upon receiving messages from other hospital devices can be validated pre-installation as being capable of fully and correctly operating when the expected message format is received. Then, once the medical device is installed at the hospital, the validation of the software can be completed by showing that the translation module **2415** is able to provide messages of the expected format to the newly installed device. In this way, FDA validation tasks can be apportioned to a greater extent to the pre-installation timeframe where they can be more easily carried out in a controlled manner rather than in the field.

In addition, the translation module **2415** can further help streamline FDA validation, for example, when a medical device or system is expected to be installed at different hospitals whose existing devices use, for example, different implementations of the HL7 protocol. Normally, this type of situation could impose the requirement that the entire functionality of the software for the new medical device be completely validated at each hospital. However, if the translation module **2415** is used to interface between the new medical device and the hospital's existing devices, then much of the software functionality could possibly be validated a single time prior to installation, as just described. Then, once installed at each hospital, the software validation for the medical device can be completed by validating that correct message formats are received from the translation module (the translation rules for which are field-customizable). This may result in making on-site validation procedures significantly more efficient, which will advantageously enable more efficient FDA compliance in order to bring life-saving medical technology to patients more quickly by the use of field-customizable translation rules.

Patient Monitoring Reports

Devices and methods for monitoring physiological parameters such as blood oxygen saturation, pulse rate, blood pressure, and many others, are described herein. Such medical monitoring devices are often programmed with alarm limits to automatically detect when a physiological parameter has a value that is, for example, outside the range of values considered safe or healthy for that particular physiological parameter. In some embodiments, when such an alarm condition is detected, various actions can be taken. For example, the bedside medical monitor can emit an audible or visual alarm. In addition, in some cases, after the alarm condition has persisted for some set amount of time (e.g., 5 sec.), the alarm condition can be displayed at, for example, a central patient monitoring station, as described herein. Moreover, if the alarm condition continues to persist for some set amount of time (e.g., 10 sec.), the clinician assigned to care for the patient who is experiencing the alarm condition can be notified by, for example, a pager or other notification device.

The number of detected alarm conditions is, of course, dependent upon the settings for the alarm criteria that indicate an alarm condition. In some embodiments, such alarm criteria can include a threshold value, which may indicate the boundary between values for a physiological parameter that are considered safe or normal, and those that are considered to indicate a medical condition which may require attention from a clinician. The nearer such an alarm threshold is set to values that are common for that particular physiological parameter in healthy individuals under normal circumstances, the larger the number of alarm events that will be expected to be detected. Generally speaking, the closer the alarm criteria come to being satisfied by the normal expected range of values for a given physiological parameter, then the greater the odds of detecting any deviation from the normal range of values that may indicate that the patient is in need of some type of medical intervention (e.g., administration of drugs, CPR, ventilator, etc.). This can be desirable in the sense that it becomes less likely that a patient will experience medical duress without triggering an alarm, which can be referred to as a false negative.

Reduction of false negatives does not come without a cost, however. Namely, alarm criteria for physiological parameters that are successful in reducing false negatives may also increase the rate of false positives, where alarm conditions are detected even though the patient may not be experiencing any clinically significant medical duress. If false positives become too frequent, they can become burdensome to clinicians, who are responsible for investigating alarm conditions, resetting the monitoring devices from the alarm state, etc. In addition, frequent false positives can even put patients at risk by reducing the importance assigned to alarm events by clinicians, whether consciously or subconsciously. Thus, it is desirable to determine alarm criteria for medical monitoring applications that strike a satisfactory balance that limits false negatives to an acceptable rate without unduly increasing false positive alarm events. In some cases, false positives may be preferred to false negatives, especially in circumstances where the consequences of a false negative would be severe to the patient. Such a preference for maintaining the occurrence of false negatives at a relatively low rate can be reflected in the choice of alarm limit criteria. It is not necessarily the case, however, that false positives are always preferred to false negatives. Moreover, alarm criteria that may be satisfactory for one type of patient may be unsatisfactory for other types of patients. The appropriate balance between false positives and false negatives may vary for different medical monitoring applications.

For example, in the case of blood oxygen saturation monitoring, typical SpO2 values of healthy individuals may fall in the range of 95-100%. Therefore, if a patient monitoring device were configured with an SpO2 alarm threshold of 94%, the number of false positive alarm events may be relatively high. In contrast, if the SpO2 alarm threshold were set at 92%, then the number of false positives would likely be reduced, but the number of false negatives may increase beyond a satisfactory level in some medical monitoring applications. Therefore, devices and methods for providing data that would aid in the selection of an alarm threshold that would reduce false positives while still maintaining false negatives at or below a satisfactory level would be very

useful. Such devices and methods could be used for establishing alarm criteria for a wide variety of physiological parameters.

FIG. **30** is an example graph **3000** of the distribution of alarm events for a given physiological parameter as a function of alarm limit values. The graph **3000** plots the number of detected alarm conditions versus a range of alarm limit values. The graph **3000** reflects, for example, a hypothetical situation where physiological parameter alarm data is collected from a statistically-significant number of patients of a particular type (e.g., cardiac patients) over the course of a statistically-significant period of time using a range of different alarm limit values. Of course, the distribution of alarm events as a function of alarm limit values will generally vary for different physiological parameters.

The graph **3000** shows a set of linearly increasing alarm limit values on the x-axis. The corresponding number of detected alarm conditions for each alarm limit value is plotted on the y-axis. As illustrated, for this particular physiological parameter, the number of detected alarm conditions generally decreases as the alarm limit value is increased. Each bar in the graph **3000** may be representative of, for example, a combination of false positive alarm events and correctly detected alarm events (e.g., detection of an alarm event when the patient was actually in need of medical assistance).

The dashed vertical line **3002** represents one possible alarm limit threshold value. When the physiological parameter value is above the threshold indicated by the dashed vertical line **3002**, for example, an alarm condition is detected, whereas when the physiological parameter value is below the threshold, no alarm condition is detected. The dashed vertical line **3004** represents another possible alarm limit value.

As shown on the graph **3000**, the illustrated alarm limit values **3002**, **3004** are only separated by two values on the x-axis. However, the number of alarms detected using each of the two illustrated alarm thresholds **3002**, **3004** is approximately halved in going from the first alarm threshold **3002** to the second alarm threshold **3004**. Thus, in this case, the number of alarm thresholds is non-linearly related to variation in the alarm limit values. This is illustrative of the realization that, in some cases, a hospital or other patient care facility could make relatively small changes to the alarm criteria used in monitoring a physiological parameter while disparately impacting the number of detected alarms and false positives. In some cases, the number of detected alarms could be significantly reduced, for example, by reducing the number of false positives without necessarily increasing the risk of false negatives in a clinically-significant way. Even if, however, no disproportionate change in the number of false positives can be achieved with a relatively small adjustment to alarm criteria (e.g., an alarm threshold value), the techniques described herein may still be useful in some circumstances for incrementally reducing the number of false positives in a safe manner. Of course, changes to the alarm criteria used for monitoring patients are not to be taken lightly; generally speaking, hospital administrators or other responsible personnel should authorize any changes to alarm criteria.

In some embodiments, a device and/or system is provided for collecting medical monitoring information from patients in a patient care domain. For example, the medical monitoring information can be collected from a clinically-significant number of patients over a clinically-significant period of time. In some embodiments, the patient care domain is a group of patients of a similar type, or a group of patients who exhibit similar medical characteristics, conditions, defects, etc., and, as such, can also be expected to undergo monitoring alarm conditions for similar reasons. For example, the patient care domain could consist of a group of cardiac patients on a hospital floor, etc.

In some embodiments, a number of bedside patient monitors are used to collect physiological signals from the patients. The raw physiological signals can be processed by the bedside patient monitors. For example, the bedside patient monitors may perform averaging of the raw signals, filtering, etc. The bedside patient monitors may also perform computations to calculate the value of a physiological parameter. The bedside patient monitors may then output an indication of a physiological parameter value (e.g., SpO2, pulse rate, blood pressure, etc.) and its trending over time. Physiological information such as the raw physiological signals, processed physiological signals, and/or calculated physiological parameter values, for example, for each of the patients can then be transmitted to, and stored by, for example, a central repository. In some embodiments, this information is stored by a networked database such as, for example, the round-robin database **722** described herein. In some embodiments, the central repository can store medical monitoring information for the patients in a particular domain (e.g., a hospital ward) over a period of time such as a week, or a month, for example.

At the initial time of monitoring, an algorithm, or algorithms, may be applied to the raw physiological signals, processed physiological signals, and/or computed physiological parameter values for detecting whether a first set of alarm criteria are satisfied. This can be done by, for example, each bedside patient monitor for each patient in the patient care domain. The first set of alarm criteria are, for example, those criteria implemented in the patient monitoring devices that perform real-time monitoring functions to detect alarm conditions. If the alarm criteria are satisfied, then an alarm can be generated, as described herein. The central repository can also be used to store the occurrences of alarm conditions for each patient.

In some embodiments, once a statistically-significant amount of patient monitoring data has been collected at the central repository, a reporting module can access the central repository and use these data to simulate the alarm events that would have been detected had the patient monitoring devices in the patient care domain used a different set of alarm criteria than those that were actually used at the time of monitoring.

In some embodiments, the reporting module is used in conjunction with the patient monitoring systems described herein (e.g., those shown in FIGS. **1**, **2**, **6**, **7**, **19**, and others). In some embodiments, the reporting module is a server or other computing device communicatively coupled to a network of bedside patient monitoring devices, a central monitoring station, a database, and other devices that can form a patient monitoring system. The reporting module can include a processor for analyzing patient monitoring data. The reporting module can also include, for example, electronic memory for storing patient monitoring data.

In some embodiments, if the central repository includes, for example, physiological parameter trend data for each of the patients, then the reporting module can access the trend data and can re-analyze it using, for example, the same algorithm, or algorithms, previously used by the bedside patient monitoring devices for detecting whether alarm criteria are satisfied. However, in this case a second alarm criteria can be used that is different from the first alarm criteria that was used to detect alarm conditions, for

example, in real time when the patient monitoring data was actually collected. In some embodiments, the reporting module re-analyzes the stored patient monitoring data using multiple different new alarm criteria. Thus, the reporting module can generate information showing how the number of alarms detected changes as a function of changing alarm criteria.

FIG. **31** is a flow chart that illustrates a method **3100** for determining the variation in identified alarm conditions resulting from varying alarm criteria. The method **3100** begins at block **3102** where physiological parameter data is collected from a group of patients in a patient care domain. For example, the physiological parameter data can be collected by a number of different bedside patient monitoring devices distributed throughout a patient care facility. The collected physiological parameter data can include, for example, any type of information relevant to the physiological parameter being monitored and the patient from whom the physiological parameter data is being collected. Again, some examples of physiological parameter data that can be collected are raw physiological signals, processed physiological signals, calculated values of a physiological parameter, etc.

At block **3104**, the physiological parameter data is analyzed to identify alarm conditions based upon a first set of alarm criteria. The alarm criteria can be configurable so as to modify the physiological conditions that will trigger an alarm. In some embodiments, the analysis of the physiological parameter data is performed in substantially real-time by, for example, the bedside patient monitoring devices in order to detect alarm conditions as they occur. The alarm criteria will generally depend upon the particular physiological parameter being monitored. In some embodiments, the alarm criteria is a single threshold value. In some embodiments, the alarm criteria includes multiple threshold values that define, for example, an enclosed range of safe or normal values for the physiological parameter. Other types of alarm criteria can also be used.

At block **3106**, the physiological parameter data is stored at, for example, a central repository (e.g., the round-robin database **722**). In some embodiments, the central repository stores all, or substantially all, of the physiological parameter data that was collected at block **3102**. For example, the central repository can store a physiological information such as the raw physiological signals from each patient, or physiological signals that have already been processed or altered to some extent by, for example, the bedside patient monitoring devices. In addition, the central repository can store information about any alarm conditions that were detected for each patient at block **3104**. For example, the central repository can store the timing and type of each alarm condition for each patient.

At block **3108**, the physiological parameter data that was previously stored can be analyzed to identify alarm conditions based on a second alarm criteria that is different from the first criteria used at block **3104**. This analysis can be performed by, for example, the reporting module described herein. If, for example, in the case of blood oxygen saturation monitoring, detected pulse oximetry signals were analyzed at the actual time of monitoring using an alarm threshold of 94% oxygen saturation, then later at block **3108**, the pulse oximetry signals can be re-analyzed using an alarm threshold of 93% oxygen saturation, or 92% oxygen saturation, etc. This analysis of the previously-collected physiological parameter data can be used to simulate the effect of a new alarm threshold in a riskless manner, since patients can still be monitored at, for example, blocks **3102**,

3104 using alarm criteria that are already accepted and validated. This ability to simulate the effect of changing alarm criteria on the alarm conditions that are identified from physiological data is advantageous to hospitals and other patient care facilities as a means of adjusting alarm criteria to be specifically adapted for that particular hospital or patient care facility. Specially adapted alarm criteria are advantageous because alarm criteria that work well at one hospital, or for one type of patient, are not necessarily guaranteed to work well at another hospital, or for another type of patient. This can be due to differences in the type of monitoring equipment that is used, differences in patient population, differences in the type of medical care offered, differences in medical procedures implemented by clinicians, etc.

In some embodiments, the algorithm, or algorithms, that are applied by the reporting module to the collected physiological parameter data at block **3108** are the same as, or substantially similar to, those which were applied at the time of monitoring in order to detect real-time alarm conditions, though this may not be required in all embodiments. In addition, in some embodiments, the physiological parameter data stored at the central repository is the same as, or substantially similar to, the physiological parameter data to which alarm detection algorithms were applied by, for example, bedside patient monitors at the time of collection of the data. In this way, different alarm criteria can be simulated as if they had actually been used at the time of collection of the physiological parameter data to detect real-time alarm conditions.

At block **3110**, the reporting module can analyze the effect of the simulated alarm criteria on alarm conditions that are detected. For example, the reporting module can analyze the change, if any, in the number of detected alarm conditions using the new simulated alarm criteria. This information can be provided for each patient and/or for the combined group of patients, for example. In addition, the reporting module can analyze differences in the timing at which alarm conditions were detected. Generally speaking, thereporting module can analyze any change in the number, type, timing, duration, etc. of alarm conditions that are detected when using the second alarm criteria as compared to the alarm conditions detected using the first alarm criteria that were applied at the time of monitoring.

At block **3112**, the reporting module can output a report that identifies, explains, summarizes, or otherwise bears upon the effect of the simulated alarm criteria. This report can be beneficial to, for example, hospital administrators in determining whether any changes to the alarm criteria used by, for example, the bedside patient monitors are warranted. For example, as described herein, in some circumstances the alarm criteria could be changed so as to reduce the number of false positives that are detected. The reporting module enhances the ability of hospital administrators to make such decisions because it can provide information about the effect that such changes would have had if they had been previously implemented. Generally speaking, hospital administrators will have the final responsibility for determining whether changes to the alarm criteria can be safely made in order to, for example, reduce false positives without unacceptably increasing false negatives.

FIG. **32** illustrates an example report with a table **3200** showing how simulated alarm criteria affect alarm detection events. The table **3200** includes row entries for five different simulated alarm criteria, though any number of new alarm criteria could be simulated. The table **3200** includes column entries for the number of alarms detected using each simu-

lated alarm criteria. The number of alarms could be broken down, for example, according to patient, or listed as a total sum of alarms detected for all of the patients for whom physiological parameter data was collected.

The table **3200** also includes column entries for the change in the number of alarms that were detected using each of the simulated alarm criteria as compared to the number of alarms that were detected using the actual alarm criteria applied at the time of collection of the physiological parameter data. This change could be indicated as the difference in the number of alarms, the percent difference, etc.

Many other types of information and information formats exist for reporting the effect of the simulated alarm criteria. FIG. **32** illustrates only an example report that could be generated by the reporting module based upon the simulated alarm criteria. It should be understood that such reports could include a wide variety of information relating to the impact of the simulated alarm criteria to help hospital administrators make a decision as to whether changes to alarm criteria should be made. In addition, such reports can be presented in a wide variety of formats, including tables, charts, graphs, lists, spreadsheets, etc.

FIG. **33** is a flow chart that illustrates another method **3300** for determining the variation in identified alarm conditions that occur as a result of varying alarm criteria. The method **3300** is similar to the method **3100** illustrated in FIG. **31**, however, the method **3300** additionally involves determinations of, for example, the expected effect of simulated alarm limits on false positive alarms and false negative alarms.

The method **3300** can proceed through blocks **3302** and **3304** as described above with respect to the method **3100** and blocks **3102**, **3104** illustrated in FIG. **31**. At block **3306**, however, the method **3300** further includes collection of medical intervention data. The medical intervention data can include, for example, records of whether a patient required some type of medical intervention at any point in time while the physiological parameter was being monitored. Such medical interventions could include, for example, the administration of a drug, attention from a physician or nurse (e.g., non-routine attention), attention from a rapid response team, administration of a treatment or procedure, etc. The medical intervention data can also include any pertinent information about the medical intervention such as, for example, the type, the time, and the duration of the medical intervention, the medical cause that necessitated the intervention, relationship to detect alarm events, etc.

In some embodiments, the medical intervention data that is collected at block **3306** is used to determine which, if any, of the alarm conditions detected at block **3304** were false positive alarms and/or which were alarms that represented true indications of medical duress. Later, this information can be used, for example, to determine whether various simulated alarm criteria would have eliminated any identified false positive alarms or whether the simulated alarm criteria would have resulted in non-detection of any alarms that actually did indicate a need for medical intervention (e.g., resulting in a false negative). In addition, the medical intervention data can be used to identify false negatives and to determine whether simulated alarm criteria would have resulted in detection of such false negatives. This information can be analyzed and presented in a report to further aid hospital administrators in making a determination of whether to change alarm criteria used by patient monitoring devices based upon simulated alarm criteria, as described herein.

The medical intervention data can be obtained in a variety of ways. For example, medical intervention data can be recorded by clinicians as medical interventions become necessary. These records can then be manually imported into the central repository that also stores the collected physiological parameter data. Medical intervention data can be automatically imported into the central repository from the patient's electronic medical record stored in, for example, a Hospital Information System or a Clinical Information System. In some embodiments, the bedside patient monitoring devices can be configured so as to prompt clinicians to enter medical intervention data, for example, after an alarm is disabled. Other techniques for obtaining records of medical interventions can also be used.

If a record of a medical intervention that has been performed on behalf of the patient is, for example, temporally associated with the timing of a detected alarm condition (e.g., they are separated by some length of time less than a pre-determined threshold), this can be taken as a sign of an accurately detected alarm condition. For example, if a detected alarm condition is followed by a medical intervention relatively shortly thereafter, then it can be presumed that the alarm condition required medical attention. If, however, a record of a medical intervention that has been performed is not temporally associated with the timing of any detected alarm condition for that patient, then this can be an indication of a false negative since the medical condition that necessitated the intervention did not trigger an alarm. Later in the method **3300**, after various new alarm criteria have been simulated, it can be determined whether such simulated criteria would have detected the false negative, or whether the new simulated criteria would have still detected the alarm condition that was accurately detected by the alarm criteria in place at the time of monitoring.

In some embodiments, medical intervention data can include an automated estimation of whether or not a medical intervention for a given patient has taken place. An estimation of whether or not a medical intervention was required after an alarm detection event can be automatically made based upon, for example, the length of time that a clinician spent with the patient after responding to an alarm event, or whether a physician came to check on the patient within some time limit of a detected alarm event. This information can be collected using the clinician proximity detection devices and systems described herein. For example, in some embodiments, a patient monitoring device can start a timer after an alarm detection event has occurred. If the presence of a physician (e.g., as identified by a clinician token, as described herein) is detected within some predetermined amount of time, then an estimation can be made that the physician visit was in response to the alarm event. As such, the physician visit can be identified as a medical intervention. Similarly, a patient monitoring device can track the amount of time that a clinician (e.g., a nurse) spends in proximity to the patient after silencing an alarm. If the amount of time with the patient exceeds a certain threshold, then it can be inferred that some type of medical intervention was necessary in response to the alarm event.

In addition, an estimate of whether or not medical intervention was required, for example, after an alarm event can be determined by analyzing the physiological parameter data collected for that patient. For example, the reporting module can analyze the trend values for the physiological parameter and determine whether the physiological parameter continued to worsen after the alarm event was detected. In some embodiments, the reporting module can analyze the trend data to determine whether the patient's condition, as indi-

cated by the trend values of the physiological parameter, was worse 1 min. after the alarm detection event, whether it was worse 5 min. later, and/or whether it was worse 10 min. later. Different time limits can of course also be used. If such an analysis indicates that the patient's condition deteriorated after the alarm event was detected, then this can be taken as an indication that the alarm did in fact indicate that the patient was experiencing medical duress and that the alarm was not a false positive.

As just described, the medical intervention data used in the method **3300** can come from actual records of medical interventions that occurred. Alternatively, or additionally, the medical intervention data used in the method **3300** can be estimated based upon factors such as, for example, the amount of time clinicians spent with the patient in the wake of a detected alarm event or the behavior of the physiological parameter within some relevant time after a detected alarm event. Other factors and methods for estimating the occurrence of a medical intervention can also be used. While medical intervention data that results from actual clinician records may be more accurate and reliable, some such occurrences of medical interventions may go unreported. Estimated medical intervention data can be useful since the reliance upon clinicians to maintain accurate records is reduced, though the estimates may be somewhat less reliable than actual clinician records.

At block **3308**, the collected physiological parameter data and the medical intervention data can be stored in, for example, the central repository (e.g., the round-robin database **722**) for later analysis by the reporting module. The reporting module can include logic used for correlating the collected medical intervention data with the detected alarm events. For example, the logic can include rules or criteria for determining whether or not a given medical intervention for a patient was related to an alarm condition experienced by that patient. For example, in the case of medical intervention data obtained from actual clinician records, a particular medical intervention for a patient can be correlated with a detected alarm event for that patient if the medical intervention and the alarm event occurred within a certain amount of time of one another. Other methods are also possible for matching medical intervention data with corresponding detected alarm events that were possibly related to the medical intervention. For example, such a correlation can be based upon the type of medical intervention that was performed and the type of physiological parameter for which monitoring data has been obtained. Some medical interventions may be viewed as being particularly likely to be related to a specific physiological parameter. In such cases, the reporting module logic may be configured to make it more likely that such a medical intervention will be marked as being correlated with alarm events triggered by that physiological parameter.

At block **3310**, the reporting module analyzes the physiological parameter data using second alarm criteria, for example, as described with respect to FIG. **31** (e.g., block **3108**). At block **3312**, the reporting module can analyze any differences between those alarm conditions identified using the first alarm criteria versus those alarm conditions identified using simulated second alarm criteria. For example, after determining the alarm conditions that would have been detected by the second alarm criteria, the reporting module can determine how many of the true alarm conditions that were correctly identified at the actual time of monitoring using the first alarm criteria would have still been detected if the simulated alarm criteria had instead been implemented. It is desirable that such true alarm conditions still be

detected so as to avoid increasing the number of false negatives. Accordingly, information regarding the number of true alarm conditions that would go undetected using a given simulated alarm criteria can be provided to hospital administrators to aid in determining whether a proposed change to the alarm criteria should be adopted.

In addition, the reporting module can analyze the effect of the simulated alarm criteria on any false negatives that were identified based on medical intervention data. In some embodiments, the reporting module determines whether the simulated alarm criteria would have detected any false negatives that were not identified by the first alarm criteria actually used by the patient monitoring devices. This can be done, for example, by executing logic designed to determine whether any alarm conditions detected using the simulated alarm criteria are temporally correlated with a previously-identified false negative event. If, for example, an alarm condition identified by the simulated alarm criteria precedes the timing of the identified false negative by some period of time less than a given threshold, then this can be taken as an indication that the alarm condition would have been an indicator of the false negative. Other logical tests can also be applied to correlate alarm conditions detected using the simulated alarm criteria with false negatives that have been identified based on medical intervention data.

At block **3314**, the reporting module outputs a report that identifies, explains, summarizes, or otherwise bears upon the effect of the simulated alarm criteria. In some embodiments, the report can provide an indication of the effect that the simulated alarm criteria would be expected to have on not only the number of detected alarm events but also the number, percentage, proportion, etc. of, for example, previously undetected false negatives that may have been detected using the simulated alarm criteria. The report can also include an indication of, for example, the number, percentage, proportion, etc. of actual alarm conditions that were correctly identified using the first alarm criteria but may not have been identified using the second alarm criteria. The report can also include other information as well.

FIG. **34** illustrates an example report with a table **3400** showing how simulated alarm criteria affect the total number of alarm detection events as well as how the simulated alarm criteria affect, for example, false negatives and false positives. The table **3400** is similar to the table **3200** illustrated in FIG. **32**, and includes row entries for five different simulated alarm criteria. The table **3400** includes column entries for the number of alarms detected using each simulated alarm criteria. The table **3200** also includes column entries for the change in the number of alarms that were detected using each of the simulated alarm criteria as compared to the number of alarms that were detected using the actual alarm criteria applied at the time of collection of the physiological parameter data.

In addition, the table **3400** includes column entries for the estimated number or percentage of false negatives that previously went undetected but would have been detected using a particular simulated alarm criteria. The table **3400** also includes column entries for the estimated number or percentage of true alarm conditions that were correctly identified using the first alarm criteria but would not have been identified using a particular simulated alarm criteria (i.e., new false negatives resulting from the simulated alarm criteria). These values can be determined or estimated by the reporting module, as described herein. The table **3400** could also include information regarding change in false positives, for example, the number of false positives that were detected

by the first alarm criteria that would not have been detected by the simulated alarm criteria, or vice versa.

Again, FIG. **34** illustrates only an example report that could be generated by the reporting module based upon the simulated alarm criteria. It should be understood that such reports could include a wide variety of information to help hospital administrators make a decision as to whether changes to alarm criteria should be made. In addition, such reports can be presented in a wide variety of formats, including tables, charts, graphs, lists, spreadsheets, etc.

In addition to simulating alarm criteria, as described herein, the reporting module can also simulate the effect of other configuration changes in the bedside patient monitoring devices and/or a central patient monitoring station. For example, the reporting module can simulate the effect of different alarm notification delay times. As discussed herein, in some embodiments, when an alarm condition is detected, bedside patient monitors may be configured to wait until a predetermined alarm notification delay time has elapsed before transmitting notification of the alarm event to either a clinician or to a central monitoring station. In addition, the central monitoring station can likewise be configured to wait until a predetermined alarm notification delay time has elapsed before actually transmitting a notification of the detected alarm to a clinician by, for example, a page or other notification method.

These notification delay times can be useful in reducing the frequency of false positive alarm notification events when alarm conditions only transiently persist. Such transient alarm conditions may be triggered by, for example, sudden exertion or emotion. The reporting module can be useful in simulating the effect of differing notification delay times on alarm notification events. This can be useful because, for example, relatively slight modifications to the notification delay times could result in an important reduction in the number of false positives to which clinicians must respond.

FIG. **35** is a flow chart that illustrates a method **3500** for determining the variation in alarm notification events that occurs as a result of varying alarm notification delay times. The method **3500** begins at block **3502** where patients are monitored for physiological parameter alarm events, as described herein.

The method **3500** proceeds to block **3504** where alarm notification events are identified based upon a first alarm notification delay time. For example, an alarm notification event may be a notification by a bedside patient monitor to a central monitoring station of an alarm condition. In this case, the first alarm notification delay time could be measured as the elapsed time between when an alarm condition was detected at the bedside monitor and when notification of the alarm was sent to the central monitoring station. In addition, an alarm notification event may be a notification from a patient monitoring device to a clinician of an alarm condition. In this case, the first alarm notification delay time can be measured as the elapsed time between when an alarm condition was detected and when the clinician was notified.

At the initial time of monitoring, an algorithm, or algorithms, may be applied to the raw physiological signals, processed physiological signals, and/or computed physiological parameter values for detecting whether an alarm condition has persisted for the duration of the first alarm notification delay time. This can be done by, for example, each bedside patient monitor for each patient in the patient care domain. If an alarm condition persists for the duration of the first alarm notification delay time, then an alarm notification event can be recognized.

At block **3506**, physiological parameter data is collected and stored at, for example, a central repository (e.g., the round-robin database **722**), as described herein. At block **3508**, the physiological parameter data is re-analyzed by, for example, the reporting module using a second alarm notification delay time that is different from the first alarm notification delay time. If, for example, the first alarm notification delay time used by the patient monitoring device at block **3504** were 5 sec., the physiological parameter data could be re-analyzed using an alarm notification delay time of, for example, 6 sec., or 7 sec., etc. Shorter delay times could also be simulated.

In some cases, if the alarm condition is only transient in nature, a relatively small lengthening of the alarm notification delay time could result in the alarm condition ceasing before an alarm notification event is generated. In this way, adjustment of the alarm notification delay time can potentially safely reduce the number of alarm notification events to which clinicians must respond. This can in turn increase the effectiveness of patient care by allowing clinicians to focus their time on attending to alarm events that are non-transient. Of course, any change to alarm notification delay times should generally be approved by hospital administrators or other responsible personnel to ensure that, for example, increases in the alarm notification delay times do not unacceptably put patients at risk by increasing the amount of elapsed time between a detected alarm and the arrival of a clinician.

The analysis of the previously-collected physiological parameter data by the reporting module can be used to simulate the effect of a new alarm notification delay time in a riskless manner since patients can still be monitored at, for example, blocks **3502**, **3504** using a delay time that has already been accepted and validated. This ability to simulate the effect that new alarm notification delay times would have, without necessarily actually implementing them, is advantageous to hospitals and other patient care facilities as a means of adjusting alarm notification delay times to be specifically adapted for that particular hospital or patient care facility. As described herein with respect to alarm criteria, a change in the alarm notification delay times may result in significantly fewer alarm notification events without necessarily increasing the risk to patients.

At block **3510**, the reporting module can analyze differences between clinician notification events that are detected using the first alarm notification delay time as compared to those that are detected using the second alarm notification delay time. For example, the reporting module may determine whether the total number of alarm notification events decreases or increases, and by how much, in response to a change in the alarm notification delay time. This information can be presented to hospital administrators in the form of tables, charts, spreadsheets, etc. to assist them in determining whether a change in the alarm notification delay times implemented by the patient monitoring devices would be advantageous.

Clinician response time data can also be collected and stored for analysis by the reporting module. Clinician response time can be measured as, for example, the elapsed time between when a clinician is notified of an alarm condition and when the clinician arrives at the patient's room to shutoff the alarm and check the patient's status. This elapsed time can be measured by, for example, the bedside patient monitoring devices and transmitted to the central repository of data. Clinician response times can be stored for each clinician and/or for a group of clinicians as a whole. As a result, the reporting module can output information regard-

ing, for example, the maximum, minimum, and average response times for each clinician, and/or for a group of clinicians as a whole. This data may be useful to hospital administrators as an indicator of the performance of an individual clinician, or a group of clinicians, in responding to monitoring alarms in a prompt manner.

Display Features

FIGS. **36**A-B illustrate displays having layout zones including zones for parameters **3610**, a plethysmograph **3620**, a prompt window **3630**, patient information **3640**, monitor settings **3650**, monitor status **3660**, user profiles **3670**, a parameter well **3680**, pulse-to-pulse signal quality bars **3690** and soft key menus **3695**. Advantageously, each zone dynamically scales information for readability of parameters most important to the proximate user. Also, the prompt window **3630** utilizes layered messaging that temporarily overwrites a less critical portion of the display. Further, the parameter well **3680** contains parameters that the proximate user has chosen to minimize until they alarm. These and other display efficiency features are described below.

FIGS. **37**A-F illustrate displays that vary layouts and font sizes according to the number of installed parameters. Horizontal and vertical display formats are shown for displaying eight parameters (FIG. **37**A); seven parameters (FIG. **37**B); six parameters (FIG. **37**C); five parameters (FIG. **37**D); four parameters (FIG. **37**E); and three parameters (FIG. **37**F). Advantageously, font size increases with fewer installed parameters. Further, parameter layout varies according to the number of rows and spacing according to the number of installed parameters. Also, the plethysmograph display increases in size with few installed parameters. In addition, font size of text information scales according to the amount of information displayed, e.g. patient name is displayed in a smaller font when date and time information is added.

FIGS. **38**A-B illustrate displays **3800** having parameter wells **3810**. In particular, parameter values are displayed in either a main display portion or in a parameter well. Through a menu selection or by user profile activated by user proximity, a parameter is minimized to the parameter well. Advantageously, one or more parameters in the parameter well are displayed in a relatively small font. However, when a minimized parameter alarms, it is removed from the parameter well and return in a relatively larger font to the main display.

FIGS. **39**A-B illustrate enlarged parameter displays **3900**, **3901** that increase the font size of alarming parameters. In normal conditions, all parameters are display in a same sized font. When an alarm occurs, the violating parameter's actual value and limit values are displayed in a larger font and also blink to draw attention to the violation. In another embodiment, where all parameters are displayed at or near the maximum-sized font, then the alarming parameter will increase only slightly in size while all other parameters are reduced in size. Thus, the effect is an appearance that the alarming parameter is enlarged. In an embodiment, if either a single parameter alarms (FIG. **39**A) or all parameters alarm (FIG. **39**B), the background color also blinks at the same frequency so as to contrast with the blinking font, such as between a red background color and a soft red background color.

FIGS. **40-43** illustrate additional display embodiments having various advantageous features. FIGS. **40**A-B illustrate trend displays **4000** having colored alarm zones **4010** so that a user can readily identify the historical severity of a patient condition that triggers an alarm. FIG. **41** illustrate displays that invert arrow keys to match the cursor. FIGS. **43**A-B illustrate trend displays and corresponding set-up screens.

FIG. **42** illustrates a display having user-selectable jump-screens. In particular, through a menu option choice, a user can choose one of multiple jump screens, such as the seven choices shown, that they can access from the home page. In an embodiment, the default behavior for the button is the Trend-Toggle button **4231**. Other buttons are Alarm Limits **4232**, Compressed Waveform View or PI & PVI trend overlay **4233**, Mode Sensitivity **4234**, Patient Assess **4235**, Parameter Detail Toggle **4236** and User Profile Login **4237**.

Information and signals described herein can be represented using any of a variety of different technologies and techniques. For example, data, instructions, commands, information, signals, bits, symbols, and chips that can be referenced throughout the above description can be represented by voltages, currents, electromagnetic waves, magnetic fields or particles, optical fields or particles, or any combination thereof.

The various illustrative logical blocks, modules, circuits, and algorithm steps described in connection with the embodiments disclosed herein may be implemented as electronic hardware, computer software, or combinations of both. To clearly illustrate this interchangeability of hardware and software, various illustrative components, blocks, modules, circuits, and steps have been described above generally in terms of their functionality. Whether such functionality is implemented as hardware or software depends upon the particular application and design constraints imposed on the overall system. Skilled artisans can implement the described functionality in varying ways for each particular application, but such implementation decisions should not be interpreted as causing a departure from the scope of the present invention.

Depending on the embodiment, certain acts, events, or functions of any of the methods described herein can be performed in a different sequence, may be added, merged, or left out all together (e.g., not all described acts or events are necessary for the practice of the method). Moreover, in certain embodiments, acts or events may be performed concurrently, e.g., through multi-threaded processing, interrupt processing, or multiple processors, rather than sequentially.

The various illustrative logical blocks, modules, and circuits described in connection with the embodiments disclosed herein can be implemented or performed with a general purpose processor, a digital signal processor (DSP), an application specific integrated circuit (ASIC), a field programmable gate array (FPGA) or other programmable logic device, discrete gate or transistor logic, discrete hardware components, or any combination thereof designed to perform the functions described herein. A general purpose processor can be a microprocessor, conventional processor, controller, microcontroller, state machine, etc. A processor can also be implemented as a combination of computing devices, e.g., a combination of a DSP and a microprocessor, a plurality of microprocessors, one or more microprocessors in conjunction with a DSP core, or any other such configuration. In addition, the term "processing" is a broad term meant to encompass several meanings including, for example, implementing program code, executing instructions, manipulating signals, filtering, performing arithmetic operations, and the like.

The steps of a method or algorithm described in connection with the embodiments disclosed herein can be embodied directly in hardware, in a software module executed by

a processor, or in a combination of the two. A software module can reside in RAM memory, flash memory, ROM memory, EPROM memory, EEPROM memory, registers, hard disk, a removable disk, a CD-ROM, a DVD, or any other form of storage medium known in the art. A storage medium is coupled to the processor such that the processor can read information from, and write information to, the storage medium. In the alternative, the storage medium may be integral to the processor. The processor and the storage medium can reside in an ASIC. The ASIC can reside in a user terminal. In the alternative, the processor and the storage medium can reside as discrete components in a user terminal.

The modules can include, but are not limited to, any of the following: software or hardware components such as software object-oriented software components, class components and task components, processes, methods, functions, attributes, procedures, subroutines, segments of program code, drivers, firmware, microcode, circuitry, data, databases, data structures, tables, arrays, or variables.

In addition, although this invention has been disclosed in the context of certain preferred embodiments, it should be understood that certain advantages, features and aspects of the systems, devices, and methods may be realized in a variety of other embodiments. Additionally, it is contemplated that various aspects and features described herein can be practiced separately, combined together, or substituted for one another, and that a variety of combination and subcombinations of the features and aspects can be made and still fall within the scope of the invention. Furthermore, the systems and devices described above need not include all of the modules and functions described in the preferred embodiments.

What is claimed is:

1. A system configured to reduce a frequency of alarms from a physiological monitoring system, the system comprising:

a physiological sensor configured to detect signals representative of a physiological condition of a patient;

one or more processors configured to receive the detected signals and determine a physiological parameter of the patient, the one or more processors further configured to detect an alarm condition for the physiological parameter and delay a notification of the alarm condition until the alarm condition persists for a predetermined alarm notification delay time, wherein said one or more processors are configured to provide a notification of the alarm condition responsive to the alarm condition persisting through the alarm notification delay time, the one or more processors being associated with a care unit; and

a reporting module configured to simulate, using measurements obtained from the care unit, different alarm notification delay times to determine whether any of the different alarm notification delay times would have resulted in an alarm notification event, the alarm notification event for each different alarm notification delay time indicating that an alarm condition persisted for at least that alarm notification delay time, and to provide an indicator of the effect of a change in alarm notification delay time on frequency of alarm notification events; wherein the indicator is indicative of a change in the alarm notification delay time that is effective to reduce the frequency of transient or false alarms and wherein the indicator is configured to be used to program one or more physiological monitoring systems with alarm notification delay times.

2. The system of claim **1**, wherein delay of the notification comprises a delay in transmitting the notification to a central patient monitoring station.

3. The system of claim **1**, wherein delay of the notification comprises a delay in transmitting the notification to a clinician.

4. The system of claim **3**, wherein transmitting the notification to a clinician comprising transmitting to a cell phone or pager.

5. A method of reducing a frequency of alarms, the method comprising:

collecting signals representative of a physiological condition of a patient;

determining a physiological parameter of the patient;

detecting an alarm condition for the physiological parameter;

delaying notification of the alarm condition until the alarm condition persists for a predetermined alarm notification delay time;

providing a notification of the alarm condition responsive to the alarm condition persisting through the alarm notification delay time;

simulating, using measurements obtained from a care unit, different alarm notification delay times to determine whether any of the different alarm notification delay times would have resulted in an alarm notification event, the alarm notification event for each different alarm notification delay time indicating that an alarm condition persisted for at least that alarm notification delay time; and

providing an indicator of the effect of a change in alarm notification delay time on frequency of alarm notification events; wherein the indicator is indicative of a change in the alarm notification delay time that is effective to reduce the frequency of transient or false alarms and wherein the indicator is configured to be used to program one or more physiological monitoring systems with alarm notification delay times.

6. The method of claim **5**, wherein the delaying of the notification comprises delaying transmission of the notification to a central patient monitoring station.

7. The method of claim **5**, wherein the delaying of the notification comprises delaying transmission of the notification to a clinician.

8. The method of claim **7**, wherein transmission of the notification to the clinician further comprises transmission to a cell phone or pager.

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US00RE47353E

(19) **United States**
(12) **Reissued Patent**
Kiani et al.

(10) **Patent Number: US RE47,353 E**
(45) **Date of Reissued Patent: *Apr. 16, 2019**

(54) **ALARM SUSPEND SYSTEM**

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(*) Notice: This patent is subject to a terminal disclaimer.

(21) Appl. No.: **15/583,922**

(22) Filed: **May 1, 2017**

Related U.S. Patent Documents

Reissue of:
(64) Patent No.: **9,153,121**
Issued: **Oct. 6, 2015**
Appl. No.: **14/469,426**
Filed: **Aug. 26, 2014**

U.S. Applications:
(63) Continuation of application No. 14/036,496, filed on Sep. 25, 2013, now Pat. No. 8,847,740, which is a
(Continued)

(51) **Int. Cl.**
G08B 5/22 (2006.01)
A61B 5/00 (2006.01)
(Continued)

(52) **U.S. Cl.**
CPC ***G08B 25/001*** (2013.01); ***A61B 5/1455*** (2013.01); ***A61B 5/6826*** (2013.01);
(Continued)

(58) **Field of Classification Search**
CPC ... A61B 5/1455; A61B 5/6826; A61B 5/6838; A61B 5/746; A61B 256/0276; G08B 25/001; G08B 5/22
(Continued)

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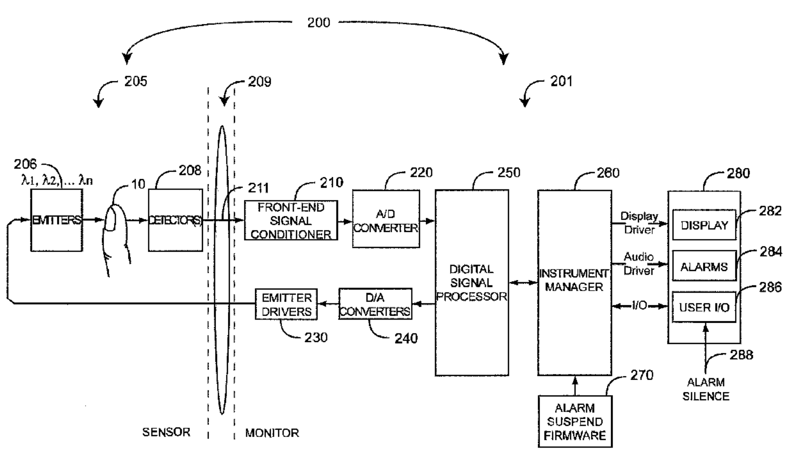
(57) **ABSTRACT**

An alarm suspend system utilizes an alarm trigger responsive to physiological parameters and corresponding limits on those parameters. The parameters are associated with both fast and slow treatment times corresponding to length of time it takes for a person to respond to medical treatment for out-of-limit parameter measurements. Audible and visual alarms respond to the alarm trigger. An alarm silence button is pressed to silence the audible alarm for a predetermined suspend time. The audible alarm is activated after the suspend time has lapsed. Longer suspend times are associated with slow treatment parameters and shorter suspend times are associated with fast treatment parameters.

25 Claims, 5 Drawing Sheets



Related U.S. Application Data

continuation of application No. 13/476,725, filed on May 21, 2012, now Pat. No. 8,547,209, which is a continuation of application No. 12/510,982, filed on Jul. 28, 2009, now Pat. No. 8,203,438.

(60) Provisional application No. 61/084,615, filed on Jul. 29, 2008.

(51) **Int. Cl.**
G08B 25/00 (2006.01)
A61B 5/1455 (2006.01)

(52) **U.S. Cl.**
CPC ***A61B 5/6838*** (2013.01); ***A61B 5/746*** (2013.01); *A61B 2560/0276* (2013.01); *G08B 5/22* (2013.01)

(58) **Field of Classification Search**
USPC .. 340/511, 517, 573.1, 539.12, 286.07, 527; 600/310, 316, 322–324, 336, 344, 507, 600/301, 320
See application file for complete search history.

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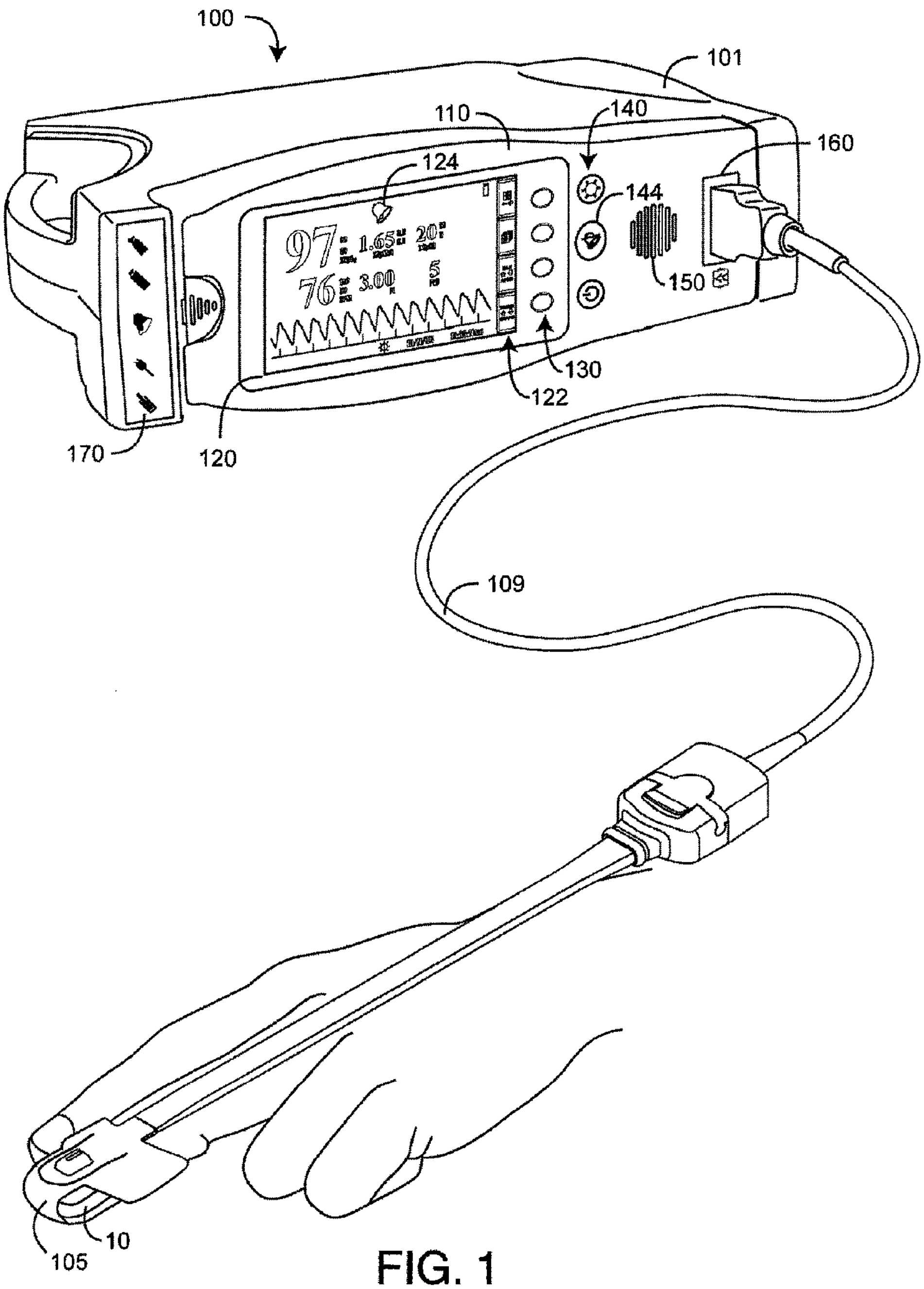
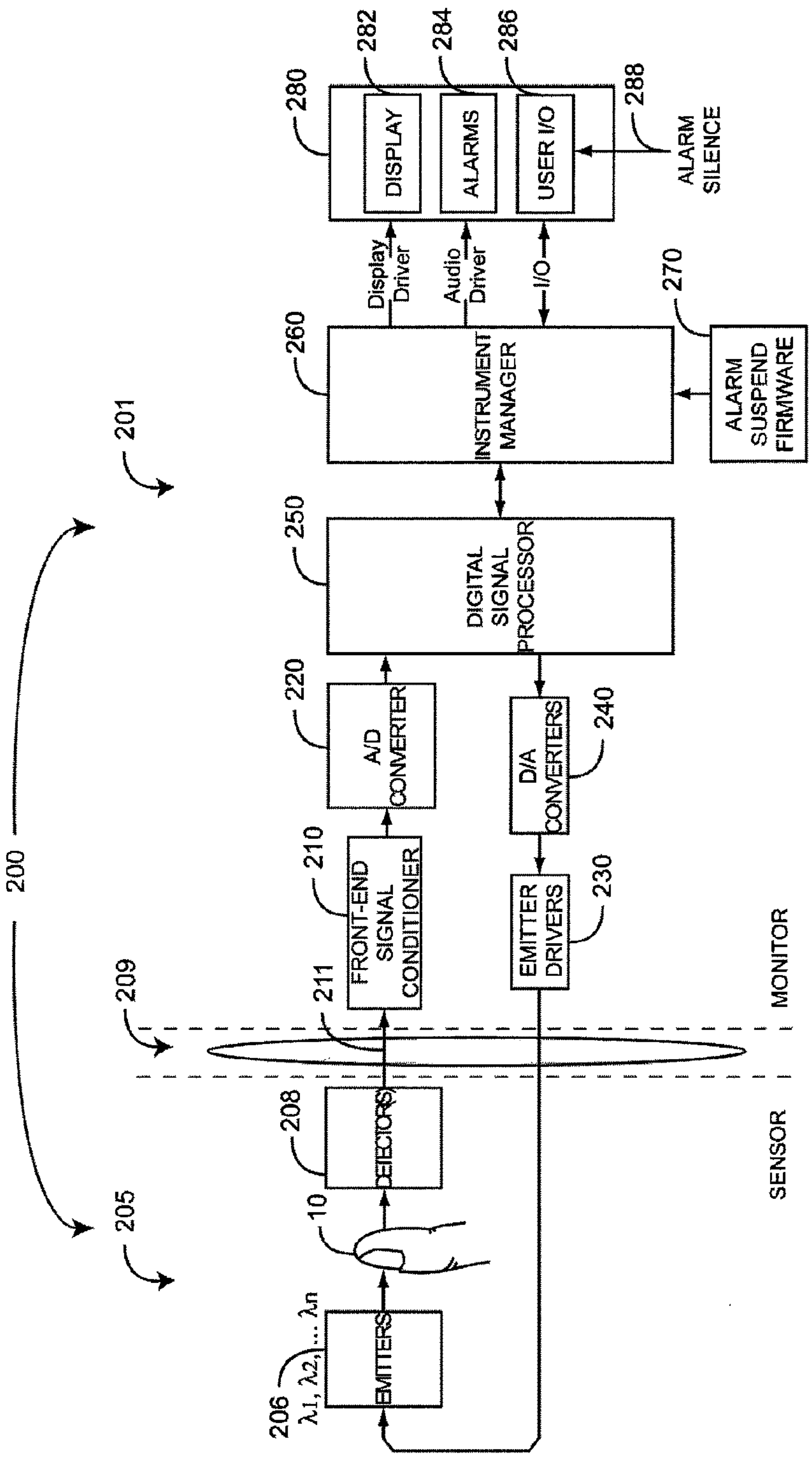
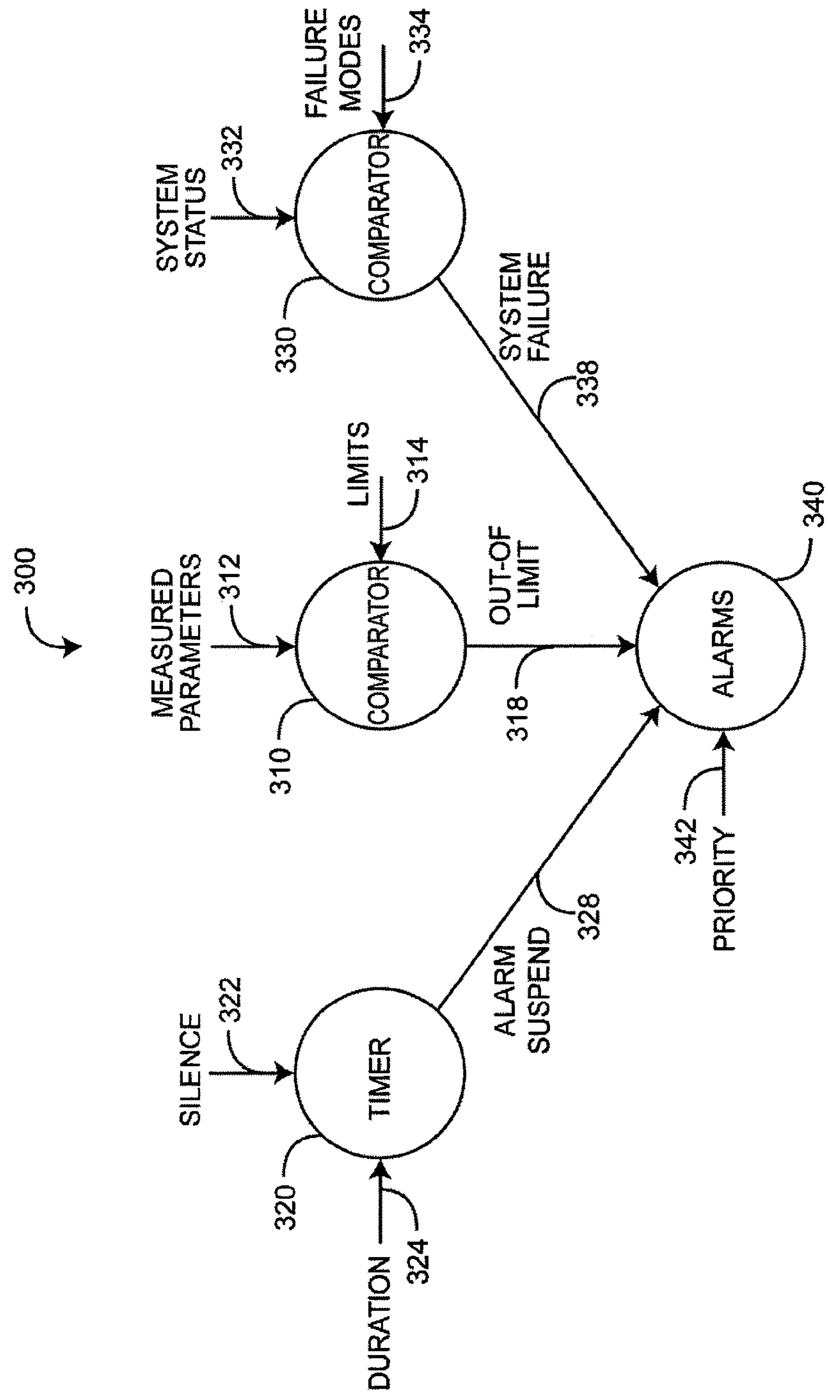


FIG. 1



200
201
205
206
λ1, λ2, ... λn
EMITTERS
10
DETECTORS
208
209
211
SENSOR
MONITOR
FRONT-END SIGNAL CONDITIONER
210
A/D CONVERTER
220
EMITTER DRIVERS
230
D/A CONVERTERS
240
DIGITAL SIGNAL PROCESSOR
250
INSTRUMENT MANAGER
260
ALARM SUSPEND FIRMWARE
270
Display Driver
Audio Driver
I/O
280
DISPLAY
282
ALARMS
284
USER I/O
286
288
ALARM SILENCE

FIG. 2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COMPARATOR
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OUT-OF LIMIT
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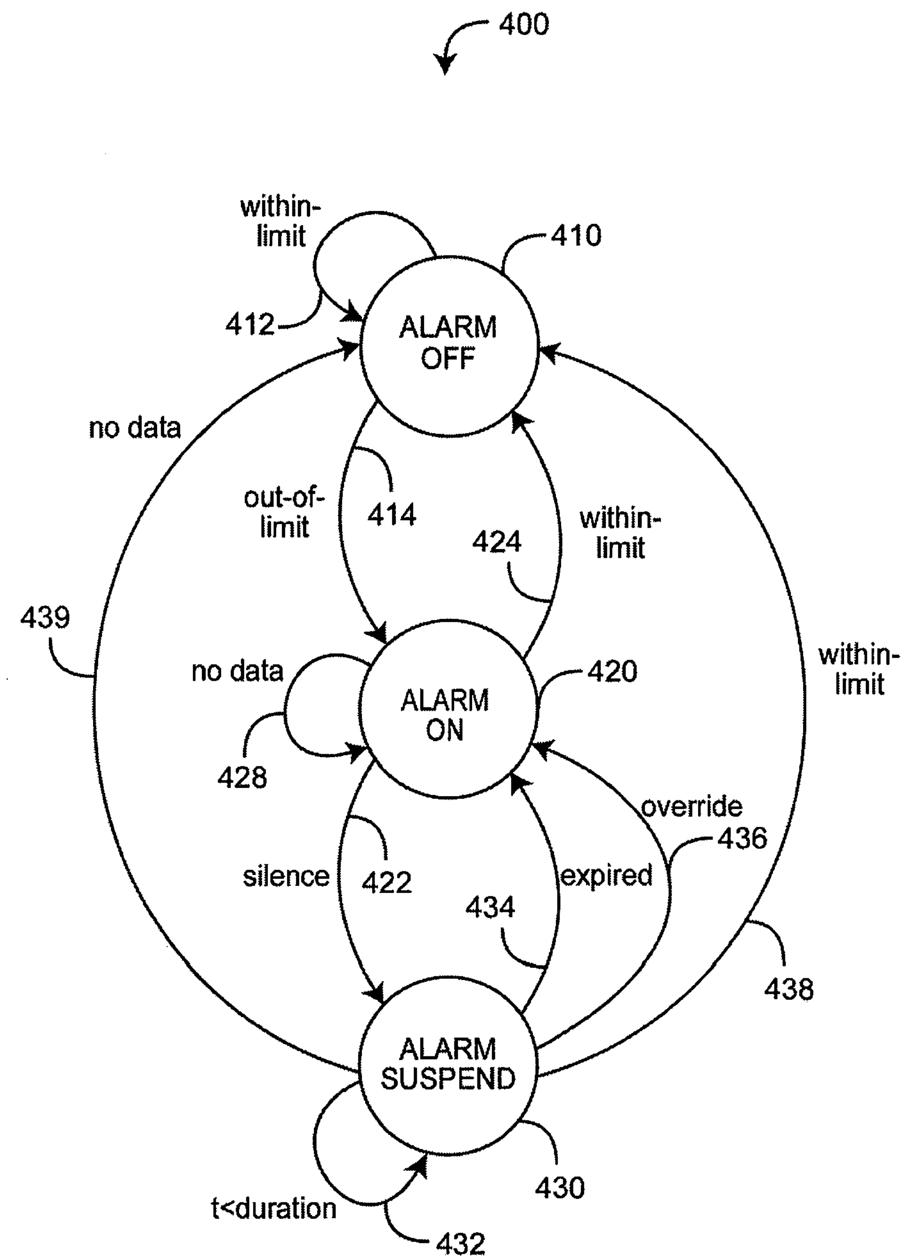
SYSTEM STATUS
332
FAILURE MODES
334
COMPARATOR
330
SYSTEM FAILURE
338
SILENCE
322
TIMER
320
DURATION
324
ALARM SUSPEND
328
ALARMS
340
PRIORITY
342

FIG. 3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412
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limit
414
424
within-
limit
439
no data
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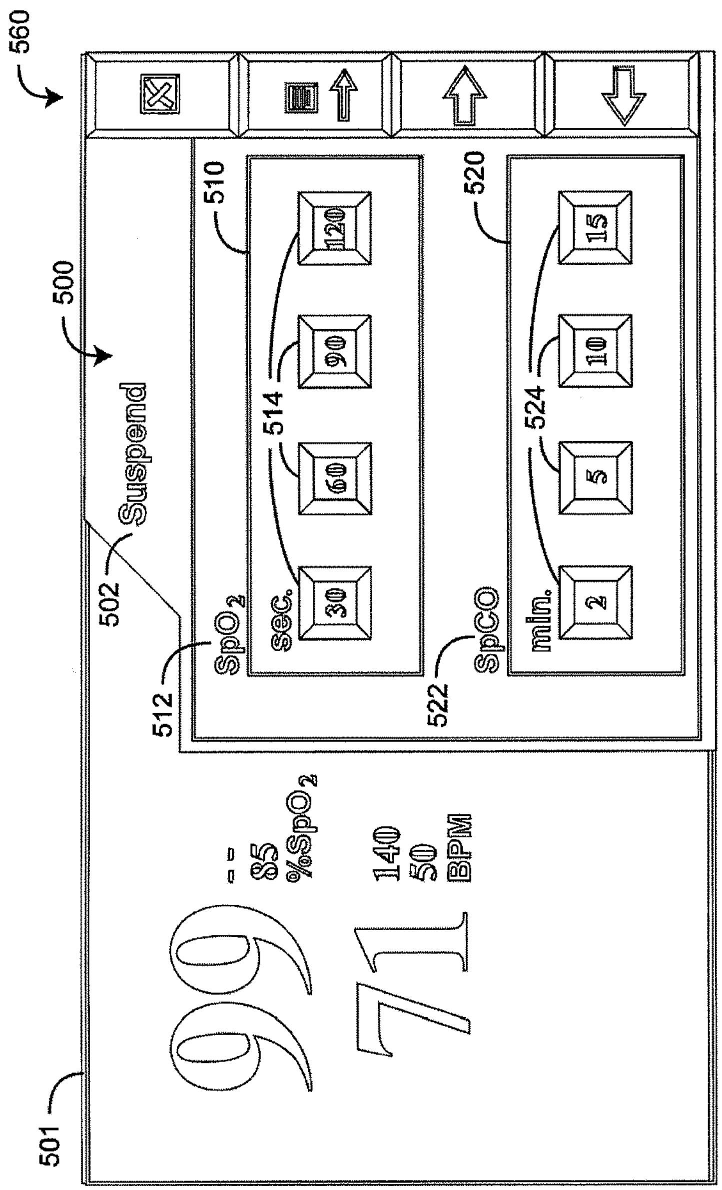
ON
420
within-
limit
428
override
436
silence
422
expired
434
438
ALARM
SUSPEND
t<duration
430
432

FIG. 4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500
501
502
Suspend
510
512
SpO_2
sec.
30
60
90
120
514
520
522
SpCO
min.
2
5
10
15
524
99
--
85
$\%SpO_2$
71
140
50
BPM

FIG. 5

ALARM SUSPEND SYSTEM

Matter enclosed in heavy brackets [ ] appears in the original patent but forms no part of this reissue specification; matter printed in italics indicates the additions made by reissue; a claim printed with strikethrough indicates that the claim was canceled, disclaimed, or held invalid by a prior post-patent action or proceeding.

CROSS-REFERENCE TO RELATED APPLICATIONS

This [application] is *an application for reissue of U.S. Pat. No. 9,153,121, issued on Oct. 6, 2015 and titled "Alarm Suspend System," which is* a continuation of U.S. patent application Ser. No. 14/036,496, filed Sep. 25, 2013 and titled "Alarm Suspend System," which is a continuation of U.S. patent application Ser. No. 13/476,725, filed May 21, 2012 and titled "Alarm Suspend System," which is a continuation of U.S. patent application Ser. No. 12/510,982 filed Jul. 28, 2009 and titled "Alarm Suspend System," which claims priority benefit under 35 U.S.C. § 119(e) to U.S. Provisional Patent Application Ser. No. 61/084,615, filed Jul. 29, 2008, titled "Alarm Management System[."]*;" more than one reissue application has been filed for the reissue of U.S. Pat. No. 9,153,121, including U.S. patent application Ser. No. 15/583,922 (the present application), U.S. patent application Ser. No. 15/583,948, and U.S. patent application Ser. No. 15/583,935.* All of the above-referenced applications are hereby incorporated by reference herein in their entireties.

BACKGROUND

Pulse oximetry for measuring constituents of circulating blood has achieved acceptance in a wide variety of medical applications, including surgical wards, intensive care and neonatal units, general wards, home care, physical training, and virtually all types of monitoring scenarios. A pulse oximeter generally includes a two-wavelength optical sensor applied to a patient, a monitor for processing sensor signals and displaying results and a patient cable electrically interconnecting the sensor and the monitor. The monitor typically provides a numerical readout of physiological parameters such as oxygen saturation (SpO_2) and pulse rate (PR). Advanced physiological monitors utilize multiple wavelength sensors and enhanced measurement capabilities to provide readouts of additional parameters, such as carboxyhemoglobin (HbCO), methemoglobin (HbMet) and total hemoglobin (Hbt).

Pulse oximeters capable of reading through motion induced noise are disclosed in at least U.S. Pat. Nos. 6,770,028, 6,658,276, 6,650,917, 6,157,850, 6,002,952, 5,769,785 and 5,758,644; low noise pulse oximetry sensors are disclosed in at least U.S. Pat. Nos. 6,088,607 and 5,782,757; all of which are assigned to Masimo Corporation, Irvine, Calif. ("Masimo") and are incorporated by reference herein.

Physiological monitors and corresponding multiple wavelength optical sensors are described in at least U.S. patent application Ser. No. 11/367,013, filed Mar. 1, 2006 and titled Multiple Wavelength Sensor Emitters and U.S. patent application Ser. No. 11/366,208, filed Mar. 1, 2006 and titled Noninvasive Multi-Parameter Patient Monitor, both assigned to Masimo Laboratories, Irvine, Calif. (Masimo Labs) and both incorporated by reference herein.

Further, physiological monitoring systems that include low noise optical sensors and pulse oximetry monitors, such as any of LNOP® adhesive or reusable sensors, SofTouch™ sensors, Hi-Fi Trauma™ or Blue™ sensors; and any of Radical®, SatShare™, Rad-9™, Rad-5™, Rad-5v™ or PPO+™ Masimo SET® pulse oximeters, are all available from Masimo. Physiological monitoring systems including multiple wavelength sensors and corresponding noninvasive blood parameter monitors, such as Rainbow™ adhesive and reusable sensors and RAD-57™ and Radical-7™ monitors for measuring SpO_2, pulse rate (PR), perfusion index (PI), pleth variability index (PVI), signal quality, HbCO and HbMet among other parameters are also available from Masimo.

SUMMARY OF THE INVENTION

Monitor alarms are triggered by out-of-limit parameters and system failures, the latter including monitor or sensor failures or improper sensor placement, to name a few. Alarms can be visual, audible or both. Alarms can also have different levels of priority, which are reflected in the type of visual and audible alarms. In an embodiment, parameters exceeding limits such as low SpO_2, high HbCO, high HbMet and low and high BPM trigger high priority alarms. System failures due to sensor off, no sensor or defective sensor also trigger high priority alarms. Parameters exceeding limits such as high SpO_2, low and high PI, low and high PVI, for example, trigger medium priority alarms. Parameters exceeding limits such as low HbCO and low HbMet along with a system low battery indication are examples of low priority alarms.

An audible alarm may be temporarily suspended by pressing an alarm silence button so as to prevent unnecessary disturbance to the patient and distraction of the caregiver. During alarm suspension, visual alarms remain active. If an alarm condition persists after a predetermined alarm suspend period, the audible alarm resumes. The alarm suspend period is typically long enough to give a caregiver sufficient time to intervene with appropriate patient treatment yet short enough to ensure that patient health is not endangered if intervention is ineffective. For conventional pulse oximetry, an alarm suspend may be, for example, a maximum of 120 seconds.

Alarm suspension on advanced blood parameter monitors is problematic. With conventional pulse oximetry, treatment for abnormal parameter measurements can be quickly applied and a patient response is typically fast. For example, a treatment for low oxygen saturation is the application of an oxygen mask or an increase in oxygen flow. By contrast, the duration of treatment for parameters measured by advanced monitors is highly dependent on the alarm-triggering parameter. For example, the treatment for high methemoglobin is the injection of methylene blue, and the patient response to such an injection is slow. When patient treatment time exceeds the maximum alarm suspend period, an audible alarm will constantly reactivate. Thus, a single alarm suspend duration for all parameters is inadequate to cope with the many different types of parameters measured by advanced monitors.

One aspect of an alarm suspend system for silencing the alarms is an alarm trigger responsive to any of various parameters and predetermined limits corresponding to the parameters, where the parameters are partitioned according to treatment time, i.e. the relative length of time it takes for a person to respond to medical treatment for a parameter measurement outside of the predetermined limits. An

audible alarm is responsive to the alarm trigger. An alarm silence button is actuated so as to suspend the audible alarm. A timer tracks the duration of the suspended alarm and is initiated by actuation of an alarm silence button. The timer retriggers the audible alarm after the timed duration has lapsed/expired. In an embodiment, a long duration suspend time is associated with slow treatment parameters and a short duration suspend time is associated with fast treatment parameters. Fast treatment parameters may include, for example, parameters relating to normal blood hemoglobin constituents and slow treatment parameters may include parameters relating to abnormal blood hemoglobin constituents.

In various embodiments, a short duration suspend time is less than or equal to about two minutes and a long duration suspended time is greater than about two minutes. A default duration associated with the fast treatment parameters is about two minutes and a default duration associated with the slow treatment parameters is about fifteen minutes. The alarm suspend system may also have an alarm suspend override responsive to a predetermined unit change in the parameter triggering a suspended alarm. The override results in reactivation of the suspended alarm. A physiological monitor having an alarm suspend system may also have a pop-up window that appears on the monitor display in response to actuation of the silence button, where the pop-up window presents a choice of alarm suspend durations.

Another aspect of an alarm suspend system is a partition of measured parameters into at least a first group and a second group. An audible alarm is triggered if at least one parameter is outside of predetermined limits. The audible alarm is suspended in response to a silence request. A first duration is associated with the first group and a second duration is associated with the second group. The audible alarm is reactivated after at least one of the first duration and the second duration. The first duration may be set so as to generally correspond to a first range of treatment times for the first group of parameters. Likewise, the second duration may be set so as to generally correspond to a second range of treatment times for the second group of parameters, where the first range of treatment times and the second range of treatment times are non-overlapping.

In various embodiments, suspended audible alarms are overridden if the triggering parameter has greater than a predetermined unit change before the suspended alarm expires according to either the first duration or the second duration. The first and second groups are defined in relation to normal hemoglobin measurements abnormal hemoglobin measurements, respectively. The first duration is set to be less than or equal to two minutes and the second duration is set to be greater than two minutes, with default durations of about two minutes corresponding to the first group and about fifteen minutes corresponding to the second group. In an embodiment, a pop-up window for a monitor display is constructed and the first duration and the second duration are selected from a range of durations presented within the pop-up window.

A further aspect of an alarm suspend system deactivates an audible alarm for one of a short duration and a long duration according to the alarm-triggering parameter. A first group of parameters is associated with the short duration and a second group of parameters is associated with the long duration. The first group and the second group are partitioned according to a fast treatment time and a short treatment time associated with the parameters. An override reactivates the audible alarm if the trigger parameter changes more than a predetermine amount during the corresponding duration. In various embodiments, the first group comprises parameters related to the measurement of normal hemoglobin and the second group comprises parameters related to the measurement of abnormal hemoglobin. The long duration is greater than about 120 seconds and the short duration is less than or equal to about 120 seconds. A pop-up window for the display allows selection of the long duration and the short duration in response to the silence button.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. **1** is a perspective view of a physiological measurement system utilizing an alarm suspend system;

FIG. **2** is a detailed block diagram of a physiological measurement system utilizing an alarm suspend system;

FIG. **3** is a flow diagram of an alarm suspend system embodiment;

FIG. **4** is a state diagram of an alarm suspend system embodiment; and

FIG. **5** is an illustration of an alarm suspend pop-up window.

DETAILED DESCRIPTION

FIG. **1** illustrates a physiological measurement system **100** that utilizes an alarm suspend system. The physiological measurement system **100** has a noninvasive sensor **105** attached to a tissue site **10**, a physiological monitor **101**, and an interface cable **109** interconnecting the monitor **101** and the sensor **105**. The physiological measurement system **100** may incorporate pulse oximetry in addition to advanced features, such as a multiple wavelength sensor and advanced processes for determining physiological parameters other than or in addition to those of pulse oximetry, such as carboxyhemoglobin, methemoglobin and total hemoglobin, as a few examples.

The monitor **101** has a front panel **110** providing a display **120**, touch keys **130**, controls **140**, a speaker **150**, a sensor port **160** and status indicators **170**. The display **120** shows parameter readouts, limits and waveforms among other items. The display **120** also has touch key icons **122** that indicate touch key **130** functions. The speaker **150** provides an audible alarm in response to physiological measurements that violate preset conditions, such as an out-of-limit parameter, as well as system failures, such as a low battery condition. The controls **140** include an alarm silence button **144** that is pressed to temporarily suspend out-of-limit parameter alarms and system alarms, such as low battery. The display **120** provides visual alarms, which include a bell-shaped alarm status indicator **124** that illuminates during an alarm condition and parameter readouts **210** and limits **220** that flash when parameters are out-of-limit. Status indicators **170** also provide visual alarms. When there are multiple alarm conditions, the parameter displays **202** indicate parameters with the highest alarm priority. Touch keys **130** and corresponding icons **122** include an alarm menu access button for setting alarm conditions, such as high or low alarm limits for SpO_2, HbCO, HbMet, PR and PI. The alarm silence button **144** is pressed to temporarily suspend audible alarms. Advantageously, an alarm suspend system provides a parameter-dependent variation in the alarm suspend duration, as described below, utilizing a common silence button or other suspend initiator.

FIG. **2** illustrates a physiological measurement system **200** including a physiological monitor **201**, a sensor **205** and an interface cable **209**. The sensor **205** is attached to a tissue site, such as a finger **10**, and includes a plurality of emitters

206 irradiating the tissue site 10 with multiple wavelengths of light. The sensor 205 also includes one or more detectors 208 capable of detecting the light after attenuation by the tissue site 10. The sensor 205 transmits optical radiation at wavelengths other than or including the red and infrared wavelengths utilized in pulse oximeters. The monitor 201 inputs a corresponding sensor signal 211 and determines the relative concentrations of blood constituents other than or in addition to the "normal" blood hemoglobin constituents HbO_2 and Hb, including "abnormal" blood hemoglobin constituents HbCO, HbMet and blood related parameters such as fractional oxygen saturation, total hemoglobin and blood glucose to name a few.

As shown in FIG. 2, the monitor 201 has a front-end signal conditioner 210, an A/D converter 220, emitter drivers 230, D/A converters 240 and a digital signal processor ("DSP") 250. In general, the emitter drivers 230 convert digital control signals, via the D/A converters 240, into analog drive signals capable of driving the sensor emitters 206. The front-end signal conditioner 210 converts, via the A/D converter 220, composite analog intensity signal(s) from light sensitive detector(s) 208 into digital data input to the DSP 250. The emitter drivers 230 and front-end signal conditioner 210 communicate with the sensor 205 via the interface cable 209.

Also shown in FIG. 2, the monitor 201 has an instrument manager 260 and a user interface 280. The user interface 280 includes one or more displays 282, alarms 284 and user input/output (I/O) 286. The instrument manager 260 communicates with the DSP 250 to receive parameter data and to present that data on the display 282. The instrument manager 260 may also store and display historical or trending data related to one or more of the measured parameters or combinations of the measured parameters. The instrument manager 260 also controls audible and visual alarms and indicators 284. The instrument manager 260 responds to user-actuated keys and communicates with external devices via various I/O ports 286. Further, the instrument manager 260 executes alarm suspend firmware 270 so as to respond to an alarm silence button press 288, as described in detail with respect to FIGS. 3-4.

FIG. 3 generally illustrates an alarm suspend system 300. Alarm triggers include system failures 338 and out-of-limit parameters 318. Triggered alarms 340 may be audible, visual or both, and may vary according to priority 342. Audible alarms may be generated by a monitor front-panel-mounted speaker 150 (FIG. 1) and may vary in loudness, pitch and sound pattern. Visual alarms may include parameter labels, parameter numerics, symbols and status lights, which can flash and vary in color.

As shown in FIG. 3, measured parameters 312 are compared 310 to default or user-specified limits 314. An out-of-limit condition 318 triggers an alarm 340. An alarm suspend 328 is user-initiated by a silence request 322. This may be a press of a silence button 144 (FIG. 1) on a monitor front panel 110 (FIG. 1). In an embodiment, the alarm suspend 328 silences audible alarms and modifies the display of visual alarms. The alarm suspend 328 is based on a timer 320, which ends the alarm suspend 328 after a predetermined duration 324. The duration 324 may be a function of the out-of-limit parameter 312. In an advantageous embodiment, the duration 324 relates to, or is a function of, the treatment time for the alarm-triggering parameter so as to avoid nuisance alarms while maintaining alarm integrity.

FIG. 4 illustrates an alarm suspend embodiment 400 that operates independently for each measured parameter that

can trigger an alarm. An alarm is initially off 410. The alarm remains off as long as the parameter is within its set limits 412. If a parameter is measured outside of its set limits 414, an alarm is triggered 420. The alarm may audible, visual or both audible and visual. A user can request to silence the alarm by pressing an alarm silence button 144 (FIG. 1), for example. The silence request 422 suspends the alarm 430 which turns off audible alarms but, in an embodiment, does not deactivate visual alarms. The audible alarm remains suspended 430 for a predetermined duration 432. When the suspend duration has passed, the alarm suspend expires 434 and audible alarms are once again activated 420. The alarm remains on 428 until the triggering parameter is within limits 424 or a user once again requests silence 422. The alarm suspend 430 deactivates if the measured parameter becomes within limits 438, such as when the patient condition improves, or if no physiological data is detected 439, such as no sensor, sensor off, no cable or malfunctioning sensor situations, to name a few. Also, if the measured parameter changes during the alarm suspend 430 by a sufficient out-of-limit amount, an override 436 reactivates the audible alarms 420.

In an alarm suspend system embodiment, parameters are classified according to the typical time it takes for medical treatment to transition an out-of-limit measurement to a within-limit measurement. Suspend durations 324 (FIG. 3) are set accordingly. For example, in a two-tier embodiment, relatively slow treatment parameters, such as HbMet, HbCO, Hbt and PVI, are assigned relatively long suspend durations. Similarly, relatively fast treatment parameters, such as SpO_2 and PR, are assigned relatively short suspend durations. In an embodiment, the alarm suspend duration is adjustable for each individual parameter, including 2, 5, 10, 15, 20, 25 and 30 minutes for slow treatment parameters, with a default of 15 minutes; and 30, 60, 90 and 120 seconds for fast treatment parameters, with a default of 120 seconds. These alarm features are only active when alarm limits have been set. Other alarm features apply to both slow treatment and fast treatment parameters. For example, an alarm delay of 0, 5, 10 or 15 seconds applies to all enabled parameters.

In an embodiment, an override 436 occurs if slow treatment parameters such as HbCO, HbMet or PVI increase or Hbt decreases by a certain unit change during the alarm suspend duration. The unit change is adjustable for each parameter, such as from 1-15 in increments of 1. TABLE 1 shows a default embodiment of override unit changes for these parameters.

TABLE 1

Override Unit Changes for Selected Parameters

Parameter	Unit Change	Direction
HbCO	5	Increase
HbMet	2	Increase
Hbt	2	Decrease
PVI	OFF	Increase

FIG. 5 illustrates an alarm suspend window 500 that provides a "pop-up" display so that a monitor user may manually enter an alarm suspend duration. The alarm suspend window 500 appears as a portion of a monitor display 501, such as the front panel display 120 (FIG. 1) described above. The pop-up window 500 responds to a suspend request, such as a silence button 144 (FIG. 1) press. The alarm suspend window 500 has a window identifier 502 and one or more parameter subsections 510, 520. Each param-

eter subsection **510**, **520** has a parameter identifier **512**, **522** and corresponding suspend duration options **514**, **524**. In an embodiment, specific suspend times are selected via monitor touch keys **130** (FIG. **1**) as guided by corresponding touch key icons **560**. Selected suspend times are highlighted or otherwise identified and entered, also via a touch key **130** (FIG. **1**). In an alternative embodiment, the monitor display is a touch screen and alarm suspend times are directly entered by a finger press on a specific duration "virtual button" **514**, **524**. Once one or more suspend durations are entered, the pop-up window **500** disappears from the display **501**. The alarm suspend window **500** advantageously allows a user to quickly choose an appropriate alarm suspend duration for the situation at hand, rather than relying on a predetermined or default duration.

An alarm suspend system is described above with respect to alarms triggered by measured parameters and limits associated with those measured parameters. Limits may correspond to levels of a measured parameter, such as a percentage oxygen saturation to name but one example. Limits may also correspond to trends of a measured parameter, such as a rate-of-change of oxygen saturation, for example. Limits may also correspond to patterns in a measured parameter or a comparison of one measured parameter with another measured parameter, as further examples.

An alarm suspend system is described above with respect to a two-tier grouping of parameters, such as slow treatment and fast treatment parameters and alarm suspend durations associated with those groups. Groupings of parameters with respect to alarm suspend durations may be multi-tier, such as slow, medium and fast treatment parameters, to name but one example.

An alarm suspend system has been disclosed in detail in connection with various embodiments. These embodiments are disclosed by way of examples only and are not to limit the scope of the claims that follow. One of ordinary skill in the art will appreciate many variations and modifications.

What is claimed is:

1. A physiological measurement system comprising:

a *noninvasive* physiological sensor [including: a plurality of light emitting diodes] configured to [transmit wavelengths of light onto a tissue site of a patient; and at least one detector configured to measure an indication of the wavelengths of light after attenuation by tissue of the patient and] *be positioned on a patient and* output a signal responsive [of the attenuated light] *to a physiological condition of the patient*; and

one or more processors in communication with the *noninvasive* physiological sensor, the one or more processors configured to *electronically*:

process the signal to determine a measurement of a physiological parameter based at least in part upon the signal;

determine that an alarm should be activated in response to the measurement of the physiological parameter satisfying an alarm activation threshold;

[receive, from a user,] *determine that* an [indication of] *alarm suspension should be initiated for* a parameter-specific alarm suspension period of time corresponding to the physiological parameter, the parameter-specific alarm suspension period of time being [selected from] *one of at least* a plurality of parameter-specific alarm suspension periods of time, the parameter-specific alarm suspension period of time being different from at least one other parameter-specific alarm suspension period of time corresponding to at least one other physiological parameter *for which the one or more processors are configured to determine at least one measurement*; [activate an alarm in response to determining that an alarm activation threshold has been satisfied by the physiological parameter measurement; receive an alarm suspension indication; and in response to receiving the alarm suspension indication,]

suspend the alarm for the [indicated] parameter-specific alarm suspension period of time*; and*

activate the alarm when the measurement of the physiological parameter satisfies the alarm activation threshold after the parameter-specific alarm suspension period of time has passed.

2. The physiological measurement system of claim **1**, wherein the one or more processors are further configured to:

provide a user interface to the user including at least a plurality of user-selectable elements, each of the [selectable] *plurality of user-selectable* elements corresponding to one of the plurality of parameter-specific alarm suspension periods of time.

3. The physiological measurement system of claim **2**, wherein providing the user interface further includes:

constructing a pop-up window for a display; and

displaying the plurality of user-selectable elements in the pop-up window.

4. The physiological measurement system of claim **3**, wherein the plurality of user-selectable elements are configured to allow a user to select a specific one of the plurality of parameter-specific alarm suspension periods of time.

5. The physiological measurement system of claim **4**, wherein [the] *a* selected parameter-specific alarm suspension period of time is selected by selection of one of the plurality of user-selectable elements.

6. The physiological measurement system of claim **1**, wherein the one or more processors are further configured to:

associate [the] *a* selected parameter-specific *alarm suspension* period of time [is] with the physiological parameter.

7. The physiological measurement system of claim **6**, wherein the selected parameter-specific period of time is stored in a memory device in communication with the one or more processors.

8. The physiological measurement system of claim **1**, wherein the one or more processors are further configured to:

process the signal to determine a *measurement of a* second physiological parameter [measurement] based at least in part upon the signal;

determine that a second alarm should be activated in response to the measurement of the second physiological parameter satisfying a second alarm activation threshold;

[receive, from the user,] *determine that* a second [indication of] *alarm suspension should be initiated for* a second parameter-specific alarm suspension period of time corresponding to the second physiological parameter, the second parameter-specific alarm suspension period of time being [selected from] *one of* a second plurality of parameter-specific alarm suspension periods of time; [activate a second alarm in response to determining a second alarm activation threshold has been satisfied by the second physiological parameter measurement; and in response to receiving the alarm suspension indication,]

suspend the second alarm for the [indicated] second parameter-specific alarm suspension period of time*; and*

activate the second alarm when the measurement of the second physiological parameter satisfies the second alarm activation threshold after the second parameter-specific alarm suspension period of time has passed.

9. The physiological measurement system of claim **8**, wherein the one or more processors are further configured to:

provide a user interface to the user including at least a first plurality of user-selectable elements and a second plurality of user-selectable elements, wherein each of the first plurality of user-selectable elements corresponds to one of the plurality of parameter-specific alarm suspension periods of time, and each of the second plurality of user-selectable element corresponds to one of the second plurality of parameter-specific alarm suspension periods of time.

10. The physiological measurement system of claim **9**, wherein the one or more processors are further configured to:

construct a pop-up window for a display; and

display both the first and second plurality of user-selectable elements in the pop-up window.

11. The physiological measurement system of claim **10**, wherein [the] *a* selected *first* parameter-specific alarm suspension period of time is selected by selection of one of the first plurality of user-selectable elements, and [the] *a* selected second parameter-specific alarm suspension period of time is selected by selection of one of the second plurality of user-selectable elements.

12. The physiological measurement system of claim **11**, wherein the at least one of the [first] plurality of parameter-specific alarm suspension periods of time is different from any of the second plurality of parameter-specific alarm suspension periods of time.

13. [An] *A* method *of electronically delaying an alarm while an electronically calculated measurement of a physiological parameter satisfies an alarm activation threshold, the measurement of the physiological parameter responsive to a signal from a noninvasive sensor positioned at a monitored patient, the method* comprising:

[measuring] *electronically processing a signal from a noninvasive sensor to determine a first measurement of* a *first* physiological parameter *and a second measurement of a second physiological parameter* using a patient monitoring device, the patient monitoring device including a processor and a memory device [configured to store]*;*

electronically storing, in the memory device, a *first* parameter-specific alarm suspension period of time *corresponding to the first physiological parameter and a second parameter-specific alarm suspension period of time corresponding to the second physiological parameter, the first parameter-specific alarm suspension period of time being different from the second parameter-specific alarm suspension period of time*;

electronically determining when the first measurement of the first physiological parameter satisfies a first alarm activation threshold;

[receiving, from a user, an indication of a] *electronically determining that a first alarm suspension should be initiated for the first* parameter-specific alarm suspension period of time [corresponding to the physiological parameter, the parameter-specific alarm suspension period of time being selected from a plurality of parameter-specific alarm suspension period periods of time, the parameter-specific alarm suspension period of time being different from at least one other parameter-specific alarm suspension period of time corresponding to at least one other physiological parameter; activating an alarm in response to determining an alarm activation threshold has been satisfied by the physiological parameter measurement; receiving an alarm suspension indication];

[and in response to receiving the alarm suspension indication,] *electronically* suspending [the] *a first* alarm *for the first physiological parameter* for the [indicated] *first* parameter-specific alarm suspension period of time*; and*

electronically activating the first alarm when the first measurement of the first physiological parameter satisfies the first alarm activation threshold subsequent to the first parameter-specific alarm suspension period of time passing.

14. The method of claim **13**, wherein the *first* alarm includes an audible component and a visual component, and wherein suspending the *first* alarm comprises suspending the audible component and not suspending the visual component.

15. The method of claim **13** further comprising:

providing a user interface to the user including at least a plurality of user-selectable elements, each of the [selectable] *plurality of user-selectable* elements corresponding to one of [the] *a* plurality of parameter-specific alarm suspension periods of time*,*

wherein the plurality of parameter-specific alarm suspension periods of time comprise the first parameter-specific alarm suspension period of time.

16. The method of claim **15** further comprising:

constructing a pop-up window for a display; and

displaying the plurality of user-selectable elements in the pop-up window.

17. The method of claim **16**, wherein [the] *a* selected parameter-specific alarm suspension period of time is selected by selection of one of the plurality of user-selectable elements.

18. A physiological measurement system comprising:

a *noninvasive* physiological sensor [means for outputting] *configured to output* a signal responsive to [a noninvasive measurement of attenuated light transmitted through a tissue site] *a physiological condition* of a patient;

a memory configured to store a first alarm activation threshold; and

[a processing means] *one or more processors* in communication with the *noninvasive* physiological sensor [means] and configured to:

process the signal to determine a *first* measurement of [a] *the first measured* physiological parameter based at least in part upon the signal;

[receive, from a user, an indication of a] *determine that a first alarm suspension should be initiated for a first* parameter-specific alarm suspension period of time [corresponding to the physiological parameter], the *first* parameter-specific alarm suspension period of time *corresponding to the first measured physiological parameter and* being [selected from a plurality of parameter-specific alarm suspension periods of time, the parameter-specific alarm suspension period of time being] different from [at least one other] *a second* parameter-specific alarm suspension period of time corresponding to [at least one other] *a second*

measured physiological parameter *for which the one or more processors are configured to determine a second measurement*;

[activate an alarm in response to determining an] *determine that the first measurement satisfies the first* alarm activation threshold [has been satisfied by the physiological parameter measurement; receive an alarm suspension indication]; and

[in response to receiving the alarm suspension indication,] suspend [the] *activation of a first* alarm for the [indicated] *first* parameter-specific alarm suspension period of time *and then activate the first alarm*.

19. The physiological measurement system of claim **18**, wherein the [processing means is] *one or more processors are* further configured to:

process the signal to determine [a] *the* second [physiological parameter] measurement based at least in part upon the signal;

[receive, from the user,] *determine that* a second [indication of a] *alarm suspension should be initiated for the* second parameter-specific alarm suspension period of time [corresponding to the second physiological parameter, the second parameter-specific alarm suspension period of time being selected from a second plurality of parameter-specific alarm suspension periods of time];

[activate a second alarm in response to determining a] *determine that the second measurement satisfies a* second alarm activation threshold [has been satisfied by the second physiological parameter measurement]; and

[in response to receiving the alarm suspension indication,] suspend *activation of* the second alarm for the [indicated] second parameter-specific alarm suspension period of time *and then activate the second alarm*.

20. The physiological measurement system of claim **19**, wherein the [processing means is] *one or more processors are* further configured to:

provide a user interface to the user including at least a first plurality of user-selectable elements and a second plurality of user-selectable elements, wherein each of the first plurality of user-selectable elements corresponds to one of [the] *a first* plurality of parameter-specific alarm suspension periods of time, and each of the second plurality of user-selectable [element] *elements* corresponds to one of [the] *a* second plurality of parameter-specific alarm suspension periods of time*,*

wherein the first plurality of parameter-specific alarm suspension periods of time comprise the first parameter-specific alarm suspension period of time, and the second plurality of parameter-specific alarm suspension periods of time comprise the second parameter-specific alarm suspension period of time.

21. The physiological measurement system of claim **20**, wherein [the] *a* selected *first* parameter-specific alarm suspension period of time is selected by selection of one of the first plurality of user-selectable elements, and [the] *a* selected second parameter-specific alarm suspension period of time is selected by selection of one of the second plurality of user-selectable elements.

22. The physiological measurement system of claim **21**, wherein at least one of the first plurality of parameter-specific alarm suspension periods of time is different from any of the second plurality of parameter-specific alarm suspension periods of time.

23. The physiological measurement system of claim 1, wherein the alarm comprises an audible alarm.

24. The physiological measurement system of claim 1, wherein the one or more processors are further configured to output a visual indicator with modification for the parameter-specific alarm suspension period of time and then output the visual indicator without modification.

25. The physiological measurement system of claim 1, wherein the physiological parameter is indicative of the physiological condition of a circulatory system of the patient.

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Protective Order

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

APPLE INC., Plaintiff, v. MASIMO CORPORATION and SOUND UNITED, LLC, Defendants.	)	C.A. No. 22-1377-MN-JLH **JURY TRIAL DEMANDED**
MASIMO CORPORATION, Counter-Claimant, v. APPLE INC., Counter-Defendant.	)	
APPLE INC., Plaintiff, v. MASIMO CORPORATION and SOUND UNITED, LLC, Defendants.	)	C.A. No. 22-1378-MN-JLH **JURY TRIAL DEMANDED**
MASIMO CORPORATION and CERCACOR LABORATORIES, INC., Counter-Claimants, v. APPLE INC., Counter-Defendant.	)	

AGREED PROTECTIVE ORDER
<u>REGARDING THE DISCLOSURE AND USE OF DISCOVERY MATERIAL</u>

Plaintiff and Counter-Defendant Apple Inc. ("Plaintiff"), Defendants and Counter-Claimants Masimo Corporation and Sound United, LLC and Counter-Claimant Cercacor Laboratories, Inc. (together, "Masimo") anticipate that documents, testimony, or information containing or reflecting confidential, proprietary, trade secret, and/or commercially sensitive information are likely to be disclosed or produced during the course of discovery, initial disclosures, and supplemental disclosures in these cases and request that the Court enter this Order setting forth the conditions for treating, obtaining, and using such information.

Pursuant to Rule 26(c) of the Federal Rules of Civil Procedure, the Court finds good cause for the following Agreed Protective Order Regarding the Disclosure and Use of Discovery Material ("Order" or "Protective Order").

1. **<u>PURPOSES AND LIMITATIONS</u>**

(a) Protected Material designated under the terms of this Protective Order shall be used by a Receiving Party solely for these cases, and shall not be used directly or indirectly for any other purpose whatsoever.

(b) The Parties acknowledge that this Order does not confer blanket protections on all disclosures during discovery, or in the course of making initial or supplemental disclosures under Rule 26(a). Designations under this Order shall be made with care and shall not be made absent a good faith belief that the designated material satisfies the criteria set forth below. If it comes to a Producing Party's attention that designated material does not qualify for protection at all, or does not qualify for the level of protection initially asserted, the Producing Party must promptly notify all other Parties that it is withdrawing or changing the designation.

(c) Other Proceedings. By entering this order and limiting the disclosure of information in these cases, the Court does not intend to preclude another court from finding that information may be relevant and subject to disclosure in another case. Any person or party subject to this order who becomes subject to a request or motion that would require disclosure of another party's information designated "CONFIDENTIAL," "CONFIDENTIAL - ATTORNEYS' EYES ONLY," or "CONFIDENTIAL - OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE," pursuant to this Order shall promptly notify that party of the request or motion so that the party may have an opportunity to appear and be heard on whether that information should be disclosed.

2. **DEFINITIONS**

(a) "Affiliate" means any corporation, company, or other business entity over which a Party has the power to direct or cause the direction of the management, policies, or legal actions through: (1) at least 50% ownership of voting securities; or (2) contract; or (3) other means.

(b) "Discovery Material" means all items or information, including from any non-party, regardless of the medium or manner generated, stored, or maintained (including, among other things, testimony, transcripts, or tangible things) that are produced, disclosed, or generated in connection with discovery or Rule 26(a) disclosures in these cases.

(c) "Outside Counsel" means (i) outside counsel who appear on the pleadings as counsel for a Party and (ii) partners, associates, and staff of such counsel to whom it is reasonably necessary to disclose the information for this litigation.

(d) "Patents-in-suit" means U.S. Patent Nos. D735,131, D883,279, D947,842, D962,936, 10,076,257, 10,627,783, 10,942,491, 10,987,054, 11,106,352, 11,474,483, 10,912,501, 10,912,502, 10,945,648, 10,687,743, 10,687,745, 10,722,159, 7,761,127, 8,190,223, 10,736,507,

and 10,984,911 and any other patent asserted in these cases, as well as any related patents, patent applications, provisional patent applications, continuations, and/or divisionals.

(e) "Party" means any party to these cases, including all of its officers, directors, employees, consultants, vendors, retained experts, and outside counsel and their support staffs.

(f) "Producing Party" means any Party or non-party that discloses or produces any Discovery Material in these cases.

(g) "Protected Material" means any Discovery Material that is designated as "CONFIDENTIAL," "CONFIDENTIAL - ATTORNEYS' EYES ONLY," or "CONFIDENTIAL - OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE," as provided for in this Order. Protected Material shall not include: (i) advertising materials that have been actually published or publicly disseminated; and (ii) materials that show on their face they have been disseminated to the public.

(h) "Receiving Party" means any Party who receives Discovery Material from a Producing Party.

(i) "Source Code" means computer code, scripts, assembly, binaries, object code, source code listings (e.g., file names and path structure), descriptions of source code (e.g., descriptions of declarations, functions, and parameters), object code listings and descriptions of object code, Hardware Description Language (HDL) or Register Transfer Level (RTL) files that describe the hardware design of any ASIC or other chip, and native Computer Aided Design (CAD) files that describe the hardware design of any component, the disclosure of which to another Party or non-party is likely to cause harm or competitive disadvantage to the Producing Party. To avoid any doubt, still images of CAD files are not Source Code and will not be subject to the

disclosure and review restrictions in Section 11. Still images of CAD files may be designated as "CONFIDENTIAL" or "CONFIDENTIAL - ATTORNEYS' EYES ONLY," as provided for in this Order.

3. **<u>COMPUTATION OF TIME</u>**

The computation of any period of time prescribed or allowed by this Order shall be governed by the provisions for computing time set forth in Federal Rules of Civil Procedure 6.

4. **<u>SCOPE</u>**

(a) The protections conferred by this Order cover not only Discovery Material governed by this Order as addressed herein, but also any information copied or extracted therefrom, as well as all copies, excerpts, summaries, or compilations thereof, plus testimony, conversations, or presentations by Parties or their counsel in court or in other settings that might reveal Protected Material.

(b) Nothing in this Protective Order shall prevent or restrict a Producing Party's own disclosure or use of its own Protected Material for any purpose, and nothing in this Order shall preclude any Producing Party from showing its Protected Material to an individual who prepared the Protected Material.

(c) Nothing in this Order shall be construed to prejudice any Party's right to use any Protected Material with the consent of the Producing Party or by order of the Court.

(d) This Order is without prejudice to the right of any Party to seek further or additional protection of any Discovery Material or to modify this Order in any way, including, without limitation, an order that certain matter not be produced at all.

(e) Any use of Protected Material at trial shall be governed by the orders of the trial judge and other applicable authorities. This Order does not govern the use of Protected Material at trial.

5. **DURATION**

Even after the termination of these cases, the confidentiality obligations imposed by this Order shall remain in effect until a Producing Party agrees otherwise in writing or a court order otherwise directs.

6. **ACCESS TO AND USE OF PROTECTED MATERIAL**

(a) Basic Principles. All Protected Material shall be used solely for these cases or any related appellate proceedings, and not for any other purpose whatsoever, including without limitation, any other litigation, patent prosecution or acquisition, patent reexamination or reissue proceedings, or any business or competitive purpose or function. Protected Material shall not be distributed, disclosed, or made available to anyone except as expressly provided in this Order.

(b) Patent Prosecution Bar. After the adoption of this provision by the parties, Outside Counsel and any person associated with a Party who receives a Producing Party's material designated "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" under this Protective Order or who has access to, accesses, or otherwise learns of, in whole or in part, said material designated "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" under this Protective Order shall not prepare, prosecute, supervise, advise, counsel, or assist in the preparation or prosecution of any patent application seeking a patent on behalf of the Receiving Party or its acquirer, successor, predecessor, or Affiliate in the field of non-invasive monitoring and/or consumer wearables (generally or as

described in any patent in suit) during the pendency of this Action and for two years after final termination of this action, including all appeals. To avoid any doubt, "prosecution" as used in this section does not include representing or advising a Party before a domestic or foreign agency in connection with a reissue, ex parte reexamination, covered business method review, inter partes review, opposition, cancelation, or similar proceeding; though in connection with any such foreign or domestic agency proceeding involving the patents-in-suit, any attorney who has access to, accesses, obtains, receives, or otherwise learns, in whole or in part, any other Party's "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" shall not: (i) participate in the preparation, prosecution, supervision, advice, counsel, or assistance of any amended claims; (ii) reveal a Producing Party's Protected Material to any prosecuting reexamination counsel or agent; or (iii) use a Producing Party's Protected Material for any purpose not permitted by Section 1.

(c) Secure Storage, No Export. Protected Material must be stored and maintained by a Receiving Party at a location in the United States and in a secure manner that ensures that access is limited to the persons authorized under this Order. To ensure compliance with applicable United States Export Administration Regulations, Protected Material may not be exported outside the United States or released to any foreign national, even if within the United States. This applies to such information regardless of whether it is in the form of a stand-alone document or as an exhibit, attachment, or appendix to anything, including but not limited to briefs, reports, letters to counsel, discovery responses, or court filings—whether drafts or final versions. Foreign nationals shall not include the Parties' Outside Counsel who reside in the United States, agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A, and who are identified in writing to the Producing Party. However, the Parties' Outside Counsel

may access briefs, reports, letters to counsel, discovery responses, and court filings (including drafts) that contain Protected Material for purposes of working on these cases while traveling temporarily outside the United States, exclusive of any exhibits or appendices that attach or substantially reproduce or summarize documents, data, or testimony that have been designated by any other party as Protected Material. The Parties will use their best efforts to minimize the amount of Protected Materials in those documents (including without limitation by redacting references to Protected Materials that are not necessary for the work performed outside of the United States) to help ensure the security of the Parties' Protected Materials. Also, if this case eventually requires depositions or experts located outside the United States, the parties will revisit this issue and attempt to agree about exporting specific materials to the extent necessary. The Parties agree that neither Party waives the right to seek amendment of this Protective Order by the Court, following a meet and confer, if other circumstances concerning exportation arise in this case.

(d) Legal Advice Based on Protected Material. Nothing in this Protective Order shall be construed to prevent counsel from advising their clients with respect to these cases based in whole or in part upon Protected Materials, provided counsel does not disclose the Protected Material itself except as provided in this Order.

(e) Limitations. Nothing in this Order shall restrict in any way a Producing Party's use or disclosure of its own Protected Material. Nothing in this Order shall restrict in any way the use or disclosure of Discovery Material by a Receiving Party: (i) that is or has become publicly known through no fault of the Receiving Party; (ii) that is lawfully acquired by or known to the Receiving Party independent of the Producing Party; (iii) previously produced, disclosed and/or provided by the Producing Party to the Receiving Party or a non-party without an

obligation of confidentiality and not by inadvertence or mistake; (iv) with the consent of the Producing Party; or (v) pursuant to order of the Court.

7. **DESIGNATING PROTECTED MATERIAL**

(a) Available Designations. Any Producing Party may designate Discovery Material with any of the following designations, provided that it meets the requirements for such designations as provided for herein: "CONFIDENTIAL," "CONFIDENTIAL - ATTORNEYS' EYES ONLY," or "CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE."

(b) Written Discovery and Documents and Tangible Things. Written discovery, documents (which include "electronically stored information," as that phrase is used in Federal Rule of Procedure 34), and tangible things that meet the requirements for the confidentiality designations listed in Section 7(a) may be so designated by placing the appropriate designation on every page of the written material prior to production. For digital files being produced, the Producing Party may mark each viewable page or image with the appropriate designation, and mark the medium, container, and/or communication in which the digital files were contained. In the event that original documents are produced for inspection, the original documents shall be presumed "CONFIDENTIAL – ATTORNEYS' EYES ONLY" during the inspection and re-designated, as appropriate during the copying process.

(c) Native Files. Where electronic files and documents are produced in native electronic format, such electronic files and documents shall be designated for protection under this Order by appending to the file names or designators information indicating whether the file contains "CONFIDENTIAL," "CONFIDENTIAL - ATTORNEYS' EYES ONLY," or "CONFIDENTIAL - OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE," material, or

shall use any other reasonable method for so designating Protected Materials produced in electronic format. When electronic files or documents are printed for use at deposition, in a court proceeding, or for provision in printed form to an expert or consultant pre-approved pursuant to Section 12, the party printing the electronic files or documents shall affix a legend to the printed document corresponding to the designation of the Producing Party and including the production number and designation associated with the native file. The parties reserve the right to object to the use of any image format version of a document produced in native format to the extent any information has been altered.

(d) Depositions and Testimony. Parties or testifying persons or entities may designate depositions and other testimony with the appropriate designation by indicating on the record at the time the testimony is given or by sending written notice of how portions of the transcript of the testimony are designated within fifteen (15) days of receipt of the transcript of the testimony. If no indication on the record is made, all information disclosed during a deposition shall be deemed “CONFIDENTIAL – ATTORNEYS’ EYES ONLY” until the time within which it may be appropriately designated as provided for herein has passed. Any Protected Material that is used in the taking of a deposition shall remain subject to the provisions of this Protective Order, along with the transcript pages of the deposition testimony dealing with such Protected Material. In such cases the court reporter shall be informed of this Protective Order and shall be required to operate in a manner consistent with this Protective Order. In the event the deposition is videotaped, the original and all copies of the videotape shall be marked by the video technician to indicate that the contents of the videotape are subject to this Protective Order, substantially along the lines of “This videotape contains confidential testimony used in this case and is not to be viewed or the contents thereof to be displayed or revealed except pursuant to the terms of the operative

Protective Order in this matter or pursuant to written stipulation of the parties." Counsel for any Producing Party shall have the right to exclude from oral depositions, other than the deponent, deponent's counsel, the reporter and videographer (if any), any person who is not authorized by this Protective Order to receive or access Protected Material based on the designation of such Protected Material. Such right of exclusion shall be applicable only during periods of examination or testimony regarding such Protected Material.

8. **DISCOVERY MATERIAL DESIGNATED AS "CONFIDENTIAL"**

(a) A Producing Party may designate Discovery Material as "CONFIDENTIAL" if it contains or reflects confidential, proprietary, and/or commercially sensitive information.

(b) Unless otherwise ordered by the Court, Discovery Material designated as "CONFIDENTIAL" may be disclosed only to the following:

(i) The Receiving Party's Outside Counsel, such counsel's immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;

(ii) Officers or employees of the Receiving Party, who may be, but need not be, in-house counsel for the Receiving Party, as well as their immediate paralegals and staff, to whom disclosure is reasonably necessary for this case, provided that each such person has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(iii) Any outside expert or consultant retained by the Receiving Party to assist in these cases, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current

officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director or employee of a Party or of a competitor of a Party; (c) such expert or consultant accesses the materials in the United States only, and does not transport them to or access them from any foreign jurisdiction (however, to avoid doubt, such expert or consultant may access reports (including drafts) that contain the materials for purposes of working on these cases while traveling temporarily outside the United States); and (d) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

(iv) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is an employee of the Producing Party, or identified on the document as an author, addressee, or recipient of the material in question, or if there are other indicia (such as from metadata, cover emails, or other records of distribution) that the witness has seen or had access to the document previously; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;

(v) Court reporters, stenographers and videographers retained to record testimony taken in these cases, and their staff;

(vi) The Court, jury, and court personnel;

(vii) Graphics, translation, design, trial consulting personnel, and/or other professional vendors, having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(viii) Mock jurors having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A.

(ix) Any mediator who is assigned to hear these matters, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(x) Any other person with the prior written consent of the Producing Party.

9. **DISCOVERY MATERIAL DESIGNATED AS "CONFIDENTIAL – ATTORNEYS' EYES ONLY"**

(a) A Producing Party may designate Discovery Material as "CONFIDENTIAL – ATTORNEYS' EYES ONLY" if it contains or reflects information that is extremely confidential and/or sensitive in nature and the Producing Party reasonably believes that the disclosure of such Discovery Material is likely to cause harm or significant competitive disadvantage to the Producing Party. The Parties agree that the following information, if non-public, shall be presumed to merit the "CONFIDENTIAL – ATTORNEYS' EYES ONLY" designation: trade secrets, pricing information, financial data, sales information, sales or marketing forecasts or plans, business plans, sales or marketing strategy, product development information, engineering documents, testing documents, employee information, and other non-public information of similar competitive and business sensitivity.

(b) Unless otherwise ordered by the Court, Discovery Material designated as "CONFIDENTIAL – ATTORNEYS' EYES ONLY" may be disclosed only to:

(i) The Receiving Party's Outside Counsel, provided that such Outside Counsel is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party, and such

Outside Counsel's immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;

(ii) Any outside expert or consultant retained by the Receiving Party to assist in this action, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director, or employee of a Party or of a competitor of a Party; (c) such expert or consultant is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party; (d) such expert or consultant accesses the materials in the United States only, and does not transport them to or access them from any foreign jurisdiction (however, to avoid doubt, such expert or consultant may access reports (including drafts) that contain the materials for purposes of working on these cases while traveling temporarily outside the United States); and (e) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

(iii) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is identified on the document as an author, addressee, or recipient of the material in question, or if there are other indicia (such as from testimony, metadata, cover emails, or other records of distribution) that the witness has previously seen or had access to the document or the information contained therein; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that

the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;

(iv) Court reporters, stenographers and videographers retained to record testimony taken in this action, and their staff;

(v) The Court, jury, and court personnel;

(vi) Graphics, translation, design, trial consulting personnel, and/or other professional vendors, having first agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A;

(vii) Any mediator who is assigned to hear this matter, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(viii) Any other person with the prior written consent of the Producing Party.

(c) In addition, a Party may disclose arguments and materials derived from Discovery Material designated as "CONFIDENTIAL – ATTORNEYS' EYES ONLY" to mock jurors who have signed an undertaking or agreement agreeing not to publicly disclose Protected Material and to keep any information concerning Protected Material confidential. A Party may not disclose to mock jurors any original, as-produced materials or information (including, for example, documents, deposition testimony, or interrogatory responses) produced by another Party designated as "CONFIDENTIAL - ATTORNEYS' EYES ONLY."

10. **DISCOVERY MATERIAL DESIGNATED AS "CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE"**

(a) To the extent production of Source Code becomes necessary to the prosecution or defense of the cases, a Producing Party may designate Source Code as

"CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE" if it comprises or includes confidential, proprietary, and/or trade secret Source Code.

(b) Nothing in this Order shall be construed as a representation or admission that Source Code is properly discoverable in these cases, or to obligate any Party to produce any Source Code.

(c) Unless otherwise ordered by the Court, Discovery Material designated as "CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE" shall be subject to the provisions set forth in Section 11 below, and may be disclosed, subject to Section 11 below, solely to:

(i) The Receiving Party's Outside Counsel, provided that such Outside Counsel is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party, and such Outside Counsel's immediate paralegals and staff, and any copying or clerical litigation support services working at the direction of such counsel, paralegals, and staff;

(ii) Any outside expert or consultant retained by the Receiving Party to assist in this action, provided that disclosure is only to the extent necessary to perform such work; and provided that: (a) such expert or consultant has agreed to be bound by the provisions of the Protective Order by signing a copy of Exhibit A; (b) such expert or consultant is not a current officer, director, or employee of a Party or of a competitor of a Party, nor anticipated at the time of retention to become an officer, director or employee of a Party or of a competitor of a Party; (c) such expert or consultant is not involved in competitive decision-making, as defined by *U.S. Steel v. United States*, 730 F.2d 1465, 1468 n.3 (Fed. Cir. 1984), on behalf of a Party or a competitor of a Party; (d) such expert or consultant accesses the materials in the United States only, and does not

transport them to or access them from any foreign jurisdiction; and (e) no unresolved objections to such disclosure exist after proper notice has been given to all Parties as set forth in Section 12 below;

(iii) Witnesses at depositions or hearings in these cases and the witnesses' counsel, provided however that the disclosure shall only be made to: (1) a witness who is identified on the material as an author, addressee, or recipient of the material, or if there are indicia (such as from testimony, metadata, emails, or other records of distribution) that the witness has seen or had access to the materials previously; or (2) a witness who has been designated to testify on behalf of the Producing Party on the subject matter of the material in question, provided however that the Protected Material shown to such a witness shall be limited to Protected Material of the Producing Party;

(iv) Court reporters, stenographers and videographers retained to record testimony taken in this action, and their staff;

(v) The Court, jury, and court personnel;

(vi) Any mediator who is assigned to hear this matter, and his or her staff, subject to their agreement to maintain confidentiality to the same degree as required by this Protective Order; and

(vii) Any other person with the prior written consent of the Producing Party.

11. **DISCLOSURE AND REVIEW OF SOURCE CODE**

(a) Any Source Code that is produced by Plaintiff will be made available for inspection at the San Francisco office of its outside counsel, Desmarais LLP, or any other location mutually agreed by the Parties. Any Source Code that is produced by Masimo will be made

available for inspection at the Orange County office of their outside counsel, Knobbe Martens Olsen & Bear LLP, or any other location mutually agreed by the Parties. Source Code will be made available for inspection between the hours of 8 a.m. and 6 p.m. on business days (i.e., weekdays that are not Federal holidays), although the Parties will be reasonable in accommodating reasonable requests to conduct inspections at other times.

(b) Prior to the first inspection of any requested Source Code, the Receiving Party shall provide ten (10) days' notice of its intent to review the Source Code that has been made available by the Producing Party and, if known, the specific Source Code the Receiving Party intends to inspect. The Receiving Party shall provide seven (7) days' notice prior to any additional inspections.

(c) Source Code that is designated "CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE" shall be produced for inspection and review subject to the following provisions, unless otherwise agreed by the Producing Party:

(i) All Source Code shall be made available by the Producing Party to the Receiving Party's Outside Counsel and/or experts in a secure room on a secured computer without Internet access or network access to other computers and on which all access ports have been disabled (except for one printer port), as necessary and appropriate to prevent and protect against any unauthorized copying, transmission, removal or other transfer of any Source Code outside or away from the computer on which the Source Code is provided for inspection (the "Source Code Computer" in the "Source Code Review Room"). The Producing Party shall install tools that are sufficient for viewing and searching the code produced, on the platform produced, if such tools exist and are presently used in the ordinary course of the Producing Party's business. The Receiving Party's Outside Counsel and/or experts may request that commercially available

software tools for viewing and searching Source Code be installed on the secured computer, provided, however, that (a) the Receiving Party possesses an appropriate license to such software tools; (b) the Producing Party approves such software tools (approvals will not be unreasonably denied); and (c) such other software tools are reasonably necessary for the Receiving Party to perform its review of the Source Code consistent with all of the protections herein. The Receiving Party must provide the Producing Party with the CD or DVD or other media containing such licensed software tool(s) at least seven (7) days in advance of the date upon which the Receiving Party wishes to have the additional software tools available for use on the Source Code Computer.

(ii) No recordable media or recordable devices, including without limitation sound recorders, computers, cellular telephones, peripheral equipment, cameras, CDs, DVDs, or drives of any kind, shall be permitted into the Source Code Review Room.

(iii) The Receiving Party's Outside Counsel and/or experts shall be entitled to take notes relating to the Source Code but may not copy the Source Code into the notes and may not take such notes electronically on the Source Code Computer itself or any other computer.

(iv) The Producing Party may visually monitor the activities of the Receiving Party's representatives during any Source Code review, but only to ensure that no unauthorized electronic records of the Source Code and no information concerning the Source Code are being created or transmitted in any way.

(v) No copies of all or any portion of the Source Code may leave the room in which the Source Code is inspected except as otherwise provided herein. Further, no other written or electronic record of the Source Code is permitted except as otherwise provided herein. The Producing Party shall make available a laser printer with commercially reasonable

printing speeds for on-site printing during inspection of the Source Code. The Receiving Party may print limited portions of the Source Code only when necessary to prepare court filings or pleadings or other papers (including a testifying expert's expert report). The Receiving Party may print the Source Code in 12-point font and with information necessary to later identify that Source Code, such as, but not limited to, a header or footer, that identifies the file name and directory path. Any printed portion that consists of more than fifteen (15) pages of a continuous block of Source Code shall be presumed to be excessive, and the burden shall be on the Receiving Party to demonstrate the need for such a printed copy. The Receiving Party may print out no more than 200 pages total without prior agreement from the Producing Party or order of the Court. The Receiving Party shall not print Source Code in order to review blocks of Source Code elsewhere in the first instance, i.e., as an alternative to reviewing that Source Code electronically on the Source Code Computer, as the Parties acknowledge and agree that the purpose of the protections herein would be frustrated by printing portions of code for review and analysis elsewhere, and that printing is permitted only when necessary to prepare court filings or pleadings or other papers (including a testifying expert's expert report). Upon printing any such portions of Source Code, the printed pages shall be collected by the Producing Party. The Producing Party shall Bates number, copy, and label "CONFIDENTIAL – OUTSIDE ATTORNEYS' EYES ONLY - SOURCE CODE" any pages printed by the Receiving Party. Within seven (7) days, the Producing Party shall either (i) provide one copy set of such pages to the Receiving Party or (ii) inform the Requesting Party that it objects that the printed portions are excessive and/or not done for a permitted purpose. If, after meeting and conferring, the Producing Party and the Receiving Party cannot resolve the objection, the Receiving Party shall be entitled to seek a Court resolution of whether the printed Source Code in question is narrowly tailored and was printed for a permitted purpose. The

burden shall be on the Receiving Party to demonstrate that such printed portions are no more than is reasonably necessary for a permitted purpose and not merely printed for the purposes of review and analysis elsewhere. The printed pages shall constitute part of the Source Code produced by the Producing Party in these cases.

(vi) All persons who will review a Producing Party's Source Code on behalf of a Receiving Party, including members of a Receiving Party's outside law firm, shall be identified in writing to the Producing Party at least five (5) days in advance of the first time that such person reviews such Source Code. Such identification shall be in addition to any other disclosure required under this Order. All persons viewing Source Code shall sign on each day they view Source Code a log that will include the names of persons who enter the locked room to view the Source Code and when they enter and depart. The Producing Party shall be entitled to a copy of the log upon one (1) day's advance notice to the Receiving Party.

(vii) Unless otherwise agreed in advance by the Parties in writing, following each day on which inspection is done under this Order, the Receiving Party's Outside Counsel and/or experts shall remove all notes, documents, and all other materials from the Source Code Review Room. The Producing Party shall not be responsible for any items left in the room following each inspection session, and the Receiving Party shall have no expectation of confidentiality for any items left in the room following each inspection session without a prior agreement to that effect. Proper identification of all authorized persons shall be provided prior to any access to the secure room or the computer containing Source Code. Proper identification requires showing, at a minimum, a photo identification card sanctioned by the government of any State of the United States, by the government of the United States, or by the nation state of the authorized person's current citizenship. Access to the secure room or the Source Code Computer

may be denied, at the discretion of the supplier, to any individual who fails to provide proper identification.

(viii) Other than as provided above, the Receiving Party will not copy, remove, or otherwise transfer any Source Code from the Source Code Computer including, without limitation, copying, removing, or transferring the Source Code onto any recordable media or recordable device. The Receiving Party will not transmit any Source Code in any way from the Producing Party's facilities or the offices of its Outside Counsel of record.

(ix) The Receiving Party's Outside Counsel of record may make no more than three (3) additional paper copies of any portions of the Source Code received from a Producing Party pursuant to Section 11(c)(v), not including copies attached to court filings or used at depositions, and shall maintain a log of all paper copies of the Source Code. The log shall include the names of the reviewers and/or recipients of paper copies and locations where the paper copies are stored. Upon one (1) day's advance notice to the Receiving Party by the Producing Party, the Receiving Party shall provide a copy of this log to the Producing Party.

(x) The Receiving Party's Outside Counsel of record and any person receiving a copy of any Source Code shall maintain and store any paper copies of the Source Code at their offices in a manner that prevents duplication of or unauthorized access to the Source Code, including, without limitation, storing the Source Code in a locked room or cabinet at all times when it is not in use. No more than a total of fifteen (15) individuals identified by the Receiving Party shall have access to the printed portions of Source Code (except insofar as such code appears in any court filing or expert report).

(xi) For depositions, the Receiving Party shall not bring copies of any printed Source Code. Rather, at least seven (7) days before the date of the deposition, the Receiving

Party shall notify the Producing Party about the specific portions of Source Code it wishes to use at the deposition, and the Producing Party shall bring printed copies of those portions to the deposition for use by the Receiving Party. The Producing Party shall also accommodate reasonable requests from the Receiving Party to make a Source Code Computer available at the deposition for use at the deposition. Copies of Source Code that are marked as deposition exhibits shall not be provided to the Court Reporter or attached to deposition transcripts; rather, the deposition record will identify the exhibit by its production numbers. All paper copies of Source Code brought to the deposition shall remain with the Producing Counsel's Outside Counsel for secure destruction in a timely manner following the deposition.

(xii) Except as provided in this section, absent express written permission from the Producing Party, the Receiving Party may not create electronic images, or any other images, or make electronic copies, of the Source Code from any paper copy of Source Code for use in any manner (including by way of example only, the Receiving Party may not scan the Source Code to a PDF or photograph the code). Images or copies of Source Code shall not be included in correspondence between the Parties (references to production numbers shall be used instead), and shall be omitted from pleadings and other papers whenever possible. If a Party reasonably believes that it needs to submit a portion of Source Code as part of a filing with the Court, the Parties shall meet and confer as to how to make such a filing while protecting the confidentiality of the Source Code and such Source Code will not be filed absent agreement from the Producing Party that the confidentiality protections will be adequate. If a Producing Party agrees to produce an electronic copy of all or any portion of its Source Code or provide written permission to the Receiving Party that an electronic or any other copy needs to be made for a Court filing, access to the Receiving Party's submission, communication, and/or disclosure of electronic files or other materials

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containing any portion of Source Code (paper or electronic) shall at all times be limited solely to individuals who are expressly authorized to view Source Code under the provisions of this Order. Where the Producing Party has provided the express written permission required under this provision for a Receiving Party to create electronic copies of Source Code, the Receiving Party shall maintain a log of all such electronic copies of any portion of Source Code in its possession or in the possession of its retained consultants, including the names of the reviewers and/or recipients of any such electronic copies, and the locations and manner in which the electronic copies are stored. Additionally, any such electronic copies must be labeled "CONFIDENTIAL - ATTORNEYS' EYES ONLY - SOURCE CODE" as provided for in this Order.

12. **NOTICE OF DISCLOSURE**

(a) Prior to disclosing any Protected Material to any person described in Sections 8(b)(iii), 9(b)(ii), or 10(c)(ii) (referenced below as "Person"), the Party seeking to disclose such information shall provide the Producing Party with written notice that includes:

(i) the name of the Person;

(ii) an up-to-date curriculum vitae of the Person;

(iii) the present employer and title of the Person;

(iv) an identification of all of the Person's past and current employment and consulting relationships in the past five years, including direct relationships and relationships through entities owned or controlled by the Person, including but not limited to an identification of any individual or entity with or for whom the person is employed or to whom the person provides consulting services relating to the design, development, operation, or patenting of technologies relating to non-invasive monitoring and/or consumer wearables (generally or as described in any patent in suit), or relating to the acquisition of intellectual property assets relating

to non-invasive monitoring and/or consumer wearables (generally or as described in any patent in suit);

(v) an identification of all pending patent applications on which the Person is named as an inventor, in which the Person has any ownership interest, or as to which the Person has had or anticipates in the future any involvement in advising on, consulting on, preparing, prosecuting, drafting, editing, amending, or otherwise affecting the scope of the claims; and

(vi) a list of the cases in which the Person has testified at deposition or trial within the last five (5) years.

Further, the Party seeking to disclose Protected Material shall provide such other information regarding the Person's professional activities reasonably requested by the Producing Party for it to evaluate whether good cause exists to object to the disclosure of Protected Material to the outside expert or consultant.

(b) Within ten (10) days of receipt of the disclosure of the Person, the Producing Party or Parties may object in writing to the Person for good cause. In the absence of an objection at the end of the ten (10) day period, the Person shall be deemed approved under this Protective Order. There shall be no disclosure of Protected Material to the Person prior to expiration of this ten (10) day period. If the Producing Party objects to disclosure to the Person within such ten (10) day period, the Parties shall meet and confer via telephone or in person within four (4) days following the objection and attempt in good faith to resolve the dispute on an informal basis. If the dispute is not resolved, the Party objecting to the disclosure will have four (4) days from the date of the meet and confer to seek relief from the Court and shall have the burden of proving the need for a protective order. If relief is not sought from the Court within that time, the objection

shall be deemed withdrawn. If relief is sought, designated materials shall not be disclosed to the Person in question until the Court resolves the objection.

(c) For purposes of this section, "good cause" shall include an objectively reasonable concern that the Person will, advertently or inadvertently, use or disclose Discovery Material in a way or ways that are inconsistent with the provisions contained in this Order.

(d) Prior to receiving any Protected Material under this Order, the Person must execute a copy of the "Agreement to Be Bound by Protective Order" (Exhibit A hereto) and serve it on all Parties.

(e) An initial failure to object to a Person under this Section 12 shall not preclude the nonobjecting Party from later objecting to continued access by that Person for good cause. If an objection is made, the Parties shall meet and confer via telephone or in person within seven (7) days following the objection and attempt in good faith to resolve the dispute informally. If the dispute is not resolved, the Party objecting to the disclosure will have seven (7) days from the date of the meet and confer to seek relief from the Court. The designated Person may continue to have access to information that was provided to such Person prior to the date of the objection. If a later objection is made, no further Protected Material shall be disclosed to the Person until the Court resolves the matter or the Producing Party withdraws its objection. Notwithstanding the foregoing, if the Producing Party fails to move for a protective order within seven (7) business days after the meet and confer, further Protected Material may thereafter be provided to the Person.

13. **CHALLENGING DESIGNATIONS OF PROTECTED MATERIAL**

(a) A Party shall not be obligated to challenge the propriety of any designation of Discovery Material under this Order at the time the designation is made, and a failure to do so shall not preclude a subsequent challenge thereto.

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(b) Any challenge to a designation of Discovery Material under this Order shall be written, shall be served on Outside Counsel for the Producing Party, shall particularly identify the documents or information that the Receiving Party contends should be differently designated, and shall state the grounds for the objection. Thereafter, further protection of such material shall be resolved in accordance with the following procedures:

(i) The objecting Party shall have the burden of conferring either in person, in writing, or by telephone with the Producing Party claiming protection (as well as any other interested party) in a good faith effort to resolve the dispute. The Producing Party shall have the burden of justifying the disputed designation;

(ii) Failing agreement, the Receiving Party may bring a request or motion to the Court for a ruling that the Discovery Material in question is not entitled to the status and protection of the Producing Party's designation. The Parties' entry into this Order shall not preclude or prejudice either Party from arguing for or against any designation, establish any presumption that a particular designation is valid, or alter the burden of proof that would otherwise apply in a dispute over discovery or disclosure of information;

(iii) Notwithstanding any challenge to a designation, the Discovery Material in question shall continue to be treated as designated under this Order until one of the following occurs: (a) the Party who designated the Discovery Material in question withdraws such designation in writing; or (b) the Court rules that the Discovery Material in question is not entitled to the designation.

14. **DATA SECURITY**

(a) The Receiving Party shall implement an information security management system ("ISMS") to safeguard Protected Materials, including reasonable and appropriate

administrative, physical, and technical safeguards, and network security and encryption technologies governed by written policies and procedures, which shall comply with at least one of the following standards: (a) the International Organization for Standardization's 27001 standard; (b) the National Institute of Standards and Technology's (NIST) 800-53 standard; (c) the Center for Internet Security's Critical Security Controls, Version 8; or (d) the most recently published version of another widely recognized industry or government cybersecurity framework. The Parties shall implement encryption of all Protected Materials in transit outside of network(s) covered by the Party's ISMS (and at rest, where reasonably practical). Moreover, the Parties agree not to access Protected Materials from public computers.

(b) If the Receiving Party becomes aware of any unauthorized access, use, or disclosure of Protected Materials or devices containing Protected Materials ("Data Breach"), the Receiving Party shall promptly, and in no case later than 48 hours after learning of the Data Breach, notify the Producing Party in writing and fully cooperate with the Producing Party as may be reasonably necessary to (a) determine the source, extent, or methodology of such Data Breach, (b) recover or protect Protected Materials, and/or (c) to satisfy the Producing Party's legal, contractual, or other obligations. For the avoidance of doubt, notification obligations under this section arise when the Receiving Party both (a) learns of a Data Breach, and (b) learns that any of the Producing Party's Protected Materials are potentially subject to the Data Breach. The notification obligations set forth in this section do not run from the time the Data Breach itself.

(c) If the Receiving Party is aware of a Data Breach, the Parties shall meet and confer in good faith regarding any adjustments that should be made to the discovery process and discovery schedule in these cases, potentially including but not limited to (1) additional security measures to protect Discovery Material; (2) a stay or extension of discovery pending investigation

of a Data Breach and/or implementation of additional security measures; and (3) a sworn assurance that Discovery Material will be handled in the future only by entities not impacted by the Data Breach. In the event of a Data Breach affecting Protected Material of the Designating Party, at the Designating Party's request, the Receiving Party within 10 business days shall provide a copy of its most recent ISMS policies and procedures that relate to the safeguarding of Protected Materials and that preceded the Data Breach. Further, the Receiving Party shall submit to reasonable discovery concerning the Data Breach.

15. **SUBPOENAS OR COURT ORDERS**

(a) If at any time Protected Material is subpoenaed by any court, arbitral, administrative, or legislative body, the Party to whom the subpoena or other request is directed shall immediately give prompt written notice thereof to every Party who has produced such Discovery Material and to its counsel and shall provide each such Party with an opportunity to move for a protective order regarding the production of Protected Materials implicated by the subpoena. The Producing Party must also notify in writing the party who caused the subpoena or order to issue in the other litigation that some or all of the material covered by the subpoena or order is subject to this Protective Order, and include a copy of this Protective Order. The parties agree to work together to allow the Producing Party to seek a protective order, after the filing of which the Party served with the subpoena or court order shall not produce any information designated in this action as "CONFIDENTIAL – ATTORNEYS EYES ONLY" or "CONFIDENTIAL – ATTORNEYS EYES ONLY – SOURCE CODE" before a determination on the protective order by the court from which the subpoena or order issued, unless the Party has obtained the Producing Party's permission.

16. **FILING PROTECTED MATERIAL**

(a) Absent written permission from the Producing Party or a court Order secured after appropriate notice to all interested persons, a Receiving Party may not file or disclose in the public record any Protected Material.

(b) Any Party is authorized under District of Delaware Local Rule 5.1.3 to file under seal with the Court any brief, document or materials that are designated as Protected Material under this Order. However, nothing in this section shall in any way limit or detract from this Order's requirements as to Source Code.

17. **INADVERTENT DISCLOSURE OF PRIVILEGED MATERIAL**

(a) Pursuant to Federal Rule of Evidence 502(d) and (e), the inadvertent production by a Party of Discovery Material subject to the attorney-client privilege, work-product protection, or any other applicable privilege or protection, despite the Producing Party's reasonable efforts to prescreen such Discovery Material prior to production, will not waive the applicable privilege and/or protection in any other federal or state proceeding if a request for return of such inadvertently produced Discovery Material is made promptly after the Producing Party learns of its inadvertent production. For example, the mere production of a privileged or work product protected document in this case as part of a production is not itself a waiver. Nothing in this Order shall be interpreted to require disclosure of irrelevant information or relevant information protected by the attorney-client privilege, work product doctrine, or any other applicable privilege or immunity. The parties do not waive any objections as to the production, discoverability, admissibility, or confidentiality of documents and ESI. Moreover, nothing in this Order shall be interpreted to require disclosure of information subject to privacy protections as set forth in law or

regulation, including information that may need to be produced from outside of the United States and/or may be subject to foreign laws.

(b) Upon a request from any Producing Party who has inadvertently produced Discovery Material that it believes is privileged and/or protected, each Receiving Party shall immediately return such Protected Material or Discovery Material and all copies to the Producing Party, except for any pages containing privileged markings by the Receiving Party which shall instead be destroyed and certified as such by the Receiving Party to the Producing Party.

(c) Nothing herein shall prevent the Receiving Party from preparing a record for its own use containing the date, author, addresses, and topic of the inadvertently produced Discovery Material and such other information as is reasonably necessary to identify the Discovery Material and describe its nature to the Court in any motion to compel production of the Discovery Material.

18. **INADVERTENT FAILURE TO DESIGNATE PROPERLY**

(a) The inadvertent failure by a Producing Party to designate Discovery Material as Protected Material with one of the designations provided for under this Order shall not waive any such designation provided that the Producing Party notifies all Receiving Parties that such Discovery Material is protected under one of the categories of this Order within ten (10) days of the Producing Party learning of the inadvertent failure to designate. The Producing Party shall reproduce the Protected Material with the correct confidentiality designation within five (5) days upon its notification to the Receiving Parties. Upon receiving the Protected Material with the correct confidentiality designation, the Receiving Parties shall return or securely destroy, at the Producing Party's option, all Discovery Material that was not designated properly.

(b) A Receiving Party shall not be in breach of this Order for any use of such Discovery Material before the Receiving Party receives such notice that such Discovery Material

is protected under one of the categories of this Order, unless an objectively reasonable person would have realized that the Discovery Material should have been appropriately designated with a confidentiality designation under this Order. Once a Receiving Party has received notification of the correct confidentiality designation for the Protected Material with the correct confidentiality designation, the Receiving Party shall treat such Discovery Material (subject to the exception in Section 18(c) below) at the appropriately designated level pursuant to the terms of this Order.

(c) Notwithstanding the above, a subsequent designation of "CONFIDENTIAL," "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" shall apply on a going forward basis and shall not disqualify anyone who reviewed "CONFIDENTIAL," "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" materials while the materials were not marked "CONFIDENTIAL – ATTORNEYS' EYES ONLY" or "CONFIDENTIAL – ATTORNEYS' EYES ONLY – SOURCE CODE" from engaging in the activities set forth in Section 6(b).

19. **INADVERTENT DISCLOSURE NOT AUTHORIZED BY ORDER**

(a) In the event of a disclosure of any Discovery Material pursuant to this Order to any person or persons not authorized to receive such disclosure under this Protective Order, the Party responsible for having made such disclosure, and each Party with knowledge thereof, shall immediately notify counsel for the Producing Party whose Discovery Material has been disclosed and provide to such counsel all known relevant information concerning the nature and circumstances of the disclosure. The responsible disclosing Party shall also promptly take all reasonable measures to retrieve the improperly disclosed Discovery Material and to ensure that no further or greater unauthorized disclosure and/or use thereof is made.

(b) Unauthorized or inadvertent disclosure does not change the status of Discovery Material or waive the right to hold the disclosed document or information as Protected.

20. **FINAL DISPOSITION**

(a) Not later than ninety (90) days after the Final Disposition of these cases, each Party shall return all Discovery Material of a Producing Party to the respective Outside Counsel of the Producing Party or destroy such Material, at the option of the Producing Party. For purposes of this Order, "Final Disposition" occurs after an order, mandate, or dismissal finally terminating these cases with prejudice, including all appeals.

(b) All Parties that have received any such Discovery Material shall certify in writing that all such materials have been returned to the respective Outside Counsel of the Producing Party or destroyed. Notwithstanding the provisions for return of Discovery Material, Outside Counsel may retain one set of pleadings, correspondence and attorney and consultant work product (but not document productions) for archival purposes, but must return any pleadings, correspondence, and consultant work product that contain Source Code.

21. **MISCELLANEOUS**

(a) Right to Further Relief. Nothing in this Order abridges the right of any person to seek its modification by the Court in the future. By stipulating to this Order, the Parties do not waive the right to argue that certain material may require additional or different confidentiality protections than those set forth herein.

(b) Termination of Matters and Retention of Jurisdiction. The Parties agree that the terms of this Protective Order shall survive and remain in effect after the Final Determination of the above-captioned matters. The Court shall retain jurisdiction after Final Determination of these matters to hear and resolve any disputes arising out of this Protective Order.

(c) Successors. This Order shall be binding upon the Parties hereto, their successors, and anyone, including law firms, who obtains access to Protected Material.

(d) Right to Assert Other Objections. By stipulating to the entry of this Protective Order, no Party waives any right it otherwise would have to object to disclosing or producing any information or item. Similarly, no Party waives any right to object on any ground to use in evidence of any of the material covered by this Protective Order. This Order shall not constitute a waiver of the right of any Party to claim in these cases or otherwise that any Discovery Material, or any portion thereof, is privileged or otherwise non-discoverable, or is not admissible in evidence in these cases or any other proceeding.

(e) Modification by Court. This Order is subject to further court order based upon public policy or other considerations, and the Court may modify this Order *sua sponte* in the interests of justice. The United States District Court for the District of Delaware is responsible for the interpretation and enforcement of this Order. All disputes concerning Protected Material, however designated, produced under the protection of this Order shall be resolved by the United States District Court for the District of Delaware.

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Dated: June 14, 2023

IT IS SO ORDERED this 16th day of June, 2023.

The Honorable Jennifer L. Hall
United States District Court Magistrate Judge

<u>EXHIBIT A</u>

I, ____________________________, acknowledge and declare that I have received a copy of the Protective Order ("Order") in *Apple Inc. v. Masimo Corp. et al.*, United States District Court, District of Delaware, C.A. Nos. 22-1377-MN-JLH and 22-1378-MN-JLH. Having read and understood the terms of the Order, I agree to be bound by the terms of the Order and consent to the jurisdiction of said Court for the purpose of any proceeding to enforce the terms of the Order.

Name of individual: ____

Present occupation/job description: ________________________________

____

____

Name of Company or Firm: ______________________________________

Address:____

Dated: ______________________

____
[Signature]

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